

US3822043 (Prod: Tryon Medical Partners, PLLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:55:35

All time stamps listed in this document are displayed in GMT

US3822043

Form: Participant Creation

Generated On: 26 Nov 2020 09:55:35

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 07 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

Generated On: 26 Nov 2020 09:55:35

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1944                                                                                                                                                               |
| Age                                       | 75                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 75                                                                                                                                                                         |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>                                                                                                      |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |                                                                                                                                                                            |
| White                                     | True                                                                                                                                                                       |
| Black                                     | False                                                                                                                                                                      |
| Asian                                     | False                                                                                                                                                                      |
| American Indian or Alaska Native          | False                                                                                                                                                                      |
| Native Hawaiian or other Pacific Islander | False                                                                                                                                                                      |
| Other                                     | False                                                                                                                                                                      |
| If race is Other, specify _____           |                                                                                                                                                                            |
| Unknown                                   | False                                                                                                                                                                      |
| Not reported                              | False                                                                                                                                                                      |

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:35

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 07 AUG 2020                                  |
| Month and Year of Informed Consent (derived)    | AUG 2020                                     |
| Year of Informed Consent (derived)              | 2020                                         |
| Protocol Version                                | Amendment 1 <input checked="" type="radio"/> |
|                                                 | Amendment 2 <input type="radio"/>            |
|                                                 | Amendment 3 <input type="radio"/>            |
|                                                 | Amendment 4 <input type="radio"/>            |
|                                                 | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|                                                 | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|                                                 | Inclusion/Exclusion <input type="radio"/>    |
|                                                 | Cohort Full <input type="radio"/>            |
|                                                 | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |                                              |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|                                                 | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |                                              |
| Enrollment Trigger                              | 1                                            |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:55:35

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:55:35

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | CHRONIC OBSTRUCTIVE LUNG DISEASE                                 |
| Start date (dd MMM yyyy)                          | 06 NOV 2018                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | NOV 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | GASTROESOPHAGEAL REFLUX<br>DISEASE                               |
| Start date (dd MMM yyyy)                          | 06 NOV 2018                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | NOV 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | MIXED ANXIETY AND<br>DEPRESSIVE DISORDER                         |
| Start date (dd MMM yyyy)                          | 06 NOV 2018                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | NOV 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| 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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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | MIXED HYPERLIPIDEMIA                                             |
| Start date (dd MMM yyyy)                          | 06 NOV 2018                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | NOV 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | OSTEOPOROSIS                                                     |
| Start date (dd MMM yyyy)                          | 06 NOV 2018                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | NOV 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | RESTLESS LEG SYNDROME                                            |
| Start date (dd MMM yyyy)                          | 06 NOV 2018                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | NOV 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | DIVERTICULOSIS                                                   |
| Start date (dd MMM yyyy)                          | 06 NOV 2018                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | NOV 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | POST MENOPAUSAL                                                  |
| Start date (dd MMM yyyy)                          | UN UNK 1969                                                      |
| 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 1969                                                         |
| Start Year (derived)                              | 1969                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |



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Form: Medical History (10)

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

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | PRE MELANOMA LEFT FOREARM                                        |
| Start date (dd MMM yyyy)                          | UN UNK 2014                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2014                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2014                                                         |
| Start Year (derived)                              | 2014                                                             |
| Stop Month and Year (derived)                     | JAN 2014                                                         |
| Stop Year (derived)                               | 2014                                                             |

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | STAGE IV NON SMALL CELL<br>LUNG CANCER                           |
| Start date (dd MMM yyyy)                          |                                                                  |
| Start date completely unknown                     | True                                                             |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | True                                                             |
| Start Month and Year (derived)                    |                                                                  |
| Start Year (derived)                              |                                                                  |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | LUNG NODULE                                                      |
| Start date (dd MMM yyyy)                          | 05 FEB 2014                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | FEB 2014                                                         |
| Start Year (derived)                              | 2014                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                     |
|---------------------------------------------------|-------------------------------------|
| Condition                                         | BONE METASTASIS                     |
| Start date (dd MMM yyyy)                          |                                     |
| Start date completely unknown                     | True                                |
| Condition ongoing at study entry                  | Yes <input type="radio"/>           |
|                                                   | No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                     |
| Stop date completely unknown                      | True                                |
| Start Month and Year (derived)                    |                                     |
| Start Year (derived)                              |                                     |
| Stop Month and Year (derived)                     |                                     |
| Stop Year (derived)                               |                                     |

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | STAGE IIA INVASIVE<br>MAMMARY CARCINOMA                          |
| Start date (dd MMM yyyy)                          |                                                                  |
| Start date completely unknown                     | True                                                             |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | True                                                             |
| Start Month and Year (derived)                    |                                                                  |
| Start Year (derived)                              |                                                                  |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:55:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | BIOPROSTHETIC MITRAL VALVE (PORCINE)                             |
| Start date (dd MMM yyyy)                          |                                                                  |
| Start date completely unknown                     | True                                                             |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | True                                                             |
| Start Month and Year (derived)                    |                                                                  |
| Start Year (derived)                              |                                                                  |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 07 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 13:16 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 07 AUG 2020 13:16                    |
| Height ( <i>xxx.x</i> )                   | 60.5 in                              |
| Weight ( <i>xxx.x</i> )                   | 133 lb                               |
| BMI ( <i>xxx.x</i> )                      | 25.60064 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

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 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

Generated On: 26 Nov 2020 09:55:35

|                                                                      |                                                   |
|----------------------------------------------------------------------|---------------------------------------------------|
| Date of assessment ( <i>dd MMM yyyy</i> )                            | 07 AUG 2020                                       |
| Is the participant of childbearing potential?                        | Yes <input type="radio"/>                         |
|                                                                      | No <input checked="" type="radio"/>               |
| If No, what is the reason?                                           | Surgically sterile <input type="radio"/>          |
|                                                                      | Post-menopausal <input checked="" type="radio"/>  |
|                                                                      | Partner medically sterile <input type="radio"/>   |
|                                                                      | Not reached age of Menarche <input type="radio"/> |
|                                                                      | Other <input type="radio"/>                       |
| If Partner medically sterile or Other, specify _____                 |                                                   |
| If Surgically sterile, date of surgery ( <i>dd MMM yyyy</i> ) _____  |                                                   |
| Date of surgery unknown                                              | False                                             |
| If Post-menopausal, date of last menstruation ( <i>dd MMM yyyy</i> ) | UN UNK 1969                                       |
| Date of last menstruation unknown                                    | False                                             |

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Folder: Screening

Form: Risk of Exposure

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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** True

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

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

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|                                                                                                                                        |       |
|----------------------------------------------------------------------------------------------------------------------------------------|-------|
| <b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)                                 | False |
| <b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes) | False |
| <b>Resides in a single family home</b> (i.e., detached housing)                                                                        | False |
| <b>Other</b>                                                                                                                           | False |
| <b>Specify</b>                                                                                                                         |       |

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 07 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

Generated On: 26 Nov 2020 09:55:35

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 185196

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:35

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| Height                              | ND - Not Done                                                                                          |
| Weight                              | ND - Not Done                                                                                          |
| Timepoint                           | Pre-Dose <input checked="" type="radio"/><br>Post-Dose <input type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 07 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 13:16 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 07 AUG 2020 13:16                                                                                      |
| 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)                         | 78 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 20 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 110 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 70 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| Height                              | ND - Not Done                                                                                          |
| Weight                              | ND - Not Done                                                                                          |
| Timepoint                           | Pre-Dose <input type="radio"/><br>Post-Dose <input checked="" type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 07 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 14:31 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 07 AUG 2020 14:31                                                                                      |
| Temperature (xxx.x)                 | 97.8 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 75 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 116 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 70 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

US3822043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

|                                                                                                              |                                                                    |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Was study treatment given?                                                                                   | Yes <input checked="" type="radio"/>                               |
|                                                                                                              | No <input type="radio"/>                                           |
| If No, reason not given                                                                                      | Participant declined due to Adverse Event <input type="radio"/>    |
|                                                                                                              | Physician withheld dose due to Adverse Event <input type="radio"/> |
|                                                                                                              | Death <input type="radio"/>                                        |
|                                                                                                              | Lost To Follow-Up <input type="radio"/>                            |
|                                                                                                              | Physician Decision <input type="radio"/>                           |
|                                                                                                              | Pregnancy <input type="radio"/>                                    |
|                                                                                                              | Protocol Deviation <input type="radio"/>                           |
|                                                                                                              | Study Terminated by Sponsor <input type="radio"/>                  |
|                                                                                                              | Withdrawal of Consent by Participant <input type="radio"/>         |
|                                                                                                              | Confirmed COVID-19 <input type="radio"/>                           |
|                                                                                                              | Other <input type="radio"/>                                        |
| 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)                                                                   | 07 AUG 2020                                                        |
| What was the treatment time? (00:00-23:59)                                                                   | 13:59 (24 HR)                                                      |
| Treatment Date and Time (derived)                                                                            | 07 AUG 2020 13:59                                                  |
| Which arm was used to give treatment?                                                                        | Left Arm <input checked="" type="radio"/>                          |
|                                                                                                              | Right Arm <input type="radio"/>                                    |
| What was the frequency of the study treatment dosing?                                                        | ONCE                                                               |
| What was the route of administration for the study treatment?                                                | INTRAMUSCULAR                                                      |

US3822043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 07 AUG 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 13:20 (24 HR)                        |
| Collection date and time (derived)     | 07 AUG 2020 13:20                    |

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:35

| Collection date (dd MMM yyyy) |                           |                                 | 07 AUG 2020                        |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 13:55                           | 07 AUG 2020 13:55                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3822043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 15:12

PC Open Date & Time

07 AUG 2020 14:19

PC Close Date & Time

07 AUG 2020 16:49

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 07 AUG 2020 20:19 |
| PC Open Date & Time  | 07 AUG 2020 17:44 |
| PC Close Date & Time | 08 AUG 2020 11:59 |



US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

|                                                           |                                      |
|-----------------------------------------------------------|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                             | Yes <input checked="" type="radio"/> |
|                                                           | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F               | 98.6 °F                              |
| Was any <b>MEDICATION TAKEN today for pain or fever</b> ? | 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        | 08 AUG 2020 19:40 |
| PC Open Date & Time  | 08 AUG 2020 12:00 |
| PC Close Date & Time | 09 AUG 2020 11:59 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

09 AUG 2020 19:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 19:38

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

11 AUG 2020 19:09

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

12 AUG 2020 19:59

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 19:11

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 15:13

PC Open Date & Time

07 AUG 2020 14:19

PC Close Date & Time

07 AUG 2020 16:49

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 20:20

PC Open Date & Time

07 AUG 2020 17:44

PC Close Date & Time

08 AUG 2020 11:59



US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 19:41

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 19:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 19:39

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 19:10

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 19:59

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 19:12

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 07 AUG 2020 15:13 |
| PC Open Date & Time  | 07 AUG 2020 14:19 |
| PC Close Date & Time | 07 AUG 2020 16:49 |



US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 07 AUG 2020 20:21 |
| PC Open Date & Time  | 07 AUG 2020 17:44 |
| PC Close Date & Time | 08 AUG 2020 11:59 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 08 AUG 2020 19:41 |
| PC Open Date & Time          | 08 AUG 2020 12:00 |
| PC Close Date & Time         | 09 AUG 2020 11:59 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 09 AUG 2020 19:27 |
| PC Open Date & Time          | 09 AUG 2020 12:00 |
| PC Close Date & Time         | 10 AUG 2020 11:59 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 10 AUG 2020 19:39 |
| PC Open Date & Time          | 10 AUG 2020 12:00 |
| PC Close Date & Time         | 11 AUG 2020 11:59 |



US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 11 AUG 2020 19:10 |
| PC Open Date & Time          | 11 AUG 2020 12:00 |
| PC Close Date & Time         | 12 AUG 2020 11:59 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

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

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 13 AUG 2020 19:12 |
| PC Open Date & Time          | 13 AUG 2020 12:00 |
| PC Close Date & Time         | 14 AUG 2020 11:59 |

US3822043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3822043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 02 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT2                                  |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 2 SEP 2020                                |
| Time of assessment (00:00-23:59)    | 13:43 (24 HR)                             |
| Vital Signs Date and Time (derived) | 2 SEP 2020 13:43                          |
| Temperature (xxx.x)                 | 98.5 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |                                           |
| Pulse (xxx)                         | 86 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 18 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 130 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 84 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

|                                     |                                            |
|-------------------------------------|--------------------------------------------|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 2 SEP 2020                                 |
| Time of assessment (00:00-23:59)    | 15:10 (24 HR)                              |
| Vital Signs Date and Time (derived) | 2 SEP 2020 15:10                           |
| Temperature (xxx.x)                 | 99.1 F                                     |
| Route of measurement                | Oral <input checked="" type="radio"/>      |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |                                            |
| Pulse (xxx)                         | 81 beats/min                               |
| Pulse units                         | BPM                                        |
| Respiratory Rate (xxx)              | 18 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 125 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 76 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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



US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

|                                                                                                              |                                                                    |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Was study treatment given?                                                                                   | Yes <input checked="" type="radio"/>                               |
|                                                                                                              | No <input type="radio"/>                                           |
| If No, reason not given                                                                                      | Participant declined due to Adverse Event <input type="radio"/>    |
|                                                                                                              | Physician withheld dose due to Adverse Event <input type="radio"/> |
|                                                                                                              | Death <input type="radio"/>                                        |
|                                                                                                              | Lost To Follow-Up <input type="radio"/>                            |
|                                                                                                              | Physician Decision <input type="radio"/>                           |
|                                                                                                              | Pregnancy <input type="radio"/>                                    |
|                                                                                                              | Protocol Deviation <input type="radio"/>                           |
|                                                                                                              | Study Terminated by Sponsor <input type="radio"/>                  |
|                                                                                                              | Withdrawal of Consent by Participant <input type="radio"/>         |
|                                                                                                              | Confirmed COVID-19 <input type="radio"/>                           |
|                                                                                                              | Other <input type="radio"/>                                        |
| 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)                                                                   | 02 SEP 2020                                                        |
| What was the treatment time? (00:00-23:59)                                                                   | 14:31 (24 HR)                                                      |
| Treatment Date and Time (derived)                                                                            | 02 SEP 2020 14:31                                                  |
| Which arm was used to give treatment?                                                                        | Left Arm <input checked="" type="radio"/>                          |
|                                                                                                              | Right Arm <input type="radio"/>                                    |
| What was the frequency of the study treatment dosing?                                                        | ONCE                                                               |
| What was the route of administration for the study treatment?                                                | INTRAMUSCULAR                                                      |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 2 SEP 2020                           |
| Collection time ( <i>00:00-23:59</i> ) | 14:05 (24 HR)                        |
| Collection date and time (derived)     | 2 SEP 2020 14:05                     |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:35

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

US3822043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

---

**TIMEPOINT**

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

---

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

---

Please record your **TEMPERATURE** in °F

97.4 °F

---

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

Yes ☐  
No ☒

---

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

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PC Time Stamp 02 SEP 2020 16:00

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PC Open Date & Time 02 SEP 2020 14:51

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PC Close Date & Time 02 SEP 2020 17:21

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US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 02 SEP 2020 20:54 |
| PC Open Date & Time  | 02 SEP 2020 18:16 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.9 °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

03 SEP 2020 19:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 19:41

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 20:15

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

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**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

97.5 °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

06 SEP 2020 20:16

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 20:03

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

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**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 19:35

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 16:01

PC Open Date & Time

02 SEP 2020 14:51

PC Close Date & Time

02 SEP 2020 17:21

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 20:55

PC Open Date & Time

02 SEP 2020 18:16

PC Close Date & Time

03 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 19:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 19:42

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 20:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 20:17

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 20:03

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:35

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 SEP 2020 16:01 |
| PC Open Date & Time  | 02 SEP 2020 14:51 |
| PC Close Date & Time | 02 SEP 2020 17:21 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 SEP 2020 20:55 |
| PC Open Date & Time  | 02 SEP 2020 18:16 |
| PC Close Date & Time | 03 SEP 2020 11:59 |



US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☒

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 SEP 2020 19:38 |
| PC Open Date & Time          | 03 SEP 2020 12:00 |
| PC Close Date & Time         | 04 SEP 2020 11:59 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 SEP 2020 19:43 |
| PC Open Date & Time          | 04 SEP 2020 12:00 |
| PC Close Date & Time         | 05 SEP 2020 11:59 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 SEP 2020 20:16 |
| PC Open Date & Time          | 05 SEP 2020 12:00 |
| PC Close Date & Time         | 06 SEP 2020 11:59 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 SEP 2020 20:18 |
| PC Open Date & Time          | 06 SEP 2020 12:00 |
| PC Close Date & Time         | 07 SEP 2020 11:59 |



US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 07 SEP 2020 20:03 |
| PC Open Date & Time          | 07 SEP 2020 12:00 |
| PC Close Date & Time         | 08 SEP 2020 11:59 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 08 SEP 2020 19:36 |
| PC Open Date & Time          | 08 SEP 2020 12:00 |
| PC Close Date & Time         | 09 SEP 2020 11:59 |

US3822043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

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*

US3822043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3822043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

Was Contact Attempted?

Yes ☒

No ☐

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

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 1 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                                  |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 1 OCT 2020                            |
| Time of assessment ( <i>00:00-23:59</i> ) | 13:20 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 1 OCT 2020 13:20                      |
| Temperature ( <i>xxx.x</i> )              | 98.2 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|                                           | Axillary <input type="radio"/>        |
|                                           | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 88 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 20 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 138 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 76 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:35

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 1 OCT 2020                           |
| Collection time ( <i>00:00-23:59</i> ) | 13:39 (24 HR)                        |
| Collection date and time (derived)     | 1 OCT 2020 13:39                     |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| 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 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 checked="" type="radio"/><br>Yes <input type="radio"/> |
| Date and time of submission                                                                                                                                                     | 11 OCT 2020 14:12:12                                             |
| Patient Cloud Open Date & Time                                                                                                                                                  | 07 OCT 2020 00:01                                                |
| Patient Cloud Close Date & Time                                                                                                                                                 | 11 OCT 2020 23:59                                                |



US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 00:02:39

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 78                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input checked="" type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                                |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input checked="" type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission                                                                                                                                                     | 23 OCT 2020 23:12:23                                                                                           |
| Patient Cloud Open Date & Time                                                                                                                                                  | 21 OCT 2020 00:01                                                                                              |
| Patient Cloud Close Date & Time                                                                                                                                                 | 25 OCT 2020 23:59                                                                                              |

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 01:48:21

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 00:04:20

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 00:02:07

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 61                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 68                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 75                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 82                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 89                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 96                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 21:58:37

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

|                                                                                                                                                                                 |                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                                                                                                | DAY 110                                                          |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                  |
| Date and time of submission                                                                                                                                                     | 22 NOV 2020 00:01:50                                             |
| Patient Cloud Open Date & Time                                                                                                                                                  | 22 NOV 2020 00:01                                                |
| Patient Cloud Close Date & Time                                                                                                                                                 | 26 NOV 2020 23:59                                                |

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 117                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 124                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 131                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 138                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 145

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 152                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 159                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 166

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 173

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 180                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 187                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 194                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 201                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

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25 FEB 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 208

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 215                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3822043**

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

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14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 229                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

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21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

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28 MAR 2021 00:01

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01 APR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 243                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

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[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 264                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 271                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 278                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 285                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 327                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <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"/>                                               |



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 334                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 341                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 355

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



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 362

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 369                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 376

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 383

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



**US3822043**

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

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**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 404                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 425

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 432

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 453                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 460                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 467                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 502                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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 ☐

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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06 JAN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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13 JAN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

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16 JAN 2022 00:01

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20 JAN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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27 JAN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

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**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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10 FEB 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

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13 FEB 2022 00:01

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17 FEB 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822043**

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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 ☐

**US3822043**

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

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**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3822043**

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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 ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

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10 MAR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 586

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

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

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

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

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

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

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 ☐

**US3822043**

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

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

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

Date and time of submission

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13 MAR 2022 00:01

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17 MAR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 621

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 635

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

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

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

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

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

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

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 ☐



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

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26 MAY 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3822043**

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

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02 JUN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 670                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

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

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

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05 JUN 2022 00:01

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09 JUN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 677                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 JUN 2022 00:01

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16 JUN 2022 23:59

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US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 684                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

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23 JUN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 691

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



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

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30 JUN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

DAY 698

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

**US3822043**

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

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**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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07 JUL 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 705                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

Date and time of submission

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10 JUL 2022 00:01

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14 JUL 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 712                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <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"/>                                               |

**US3822043**

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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



**US3822043**

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

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

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24 JUL 2022 00:01

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28 JUL 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 726                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 733                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 740                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 747                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 754                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 761                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 768                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3822043**

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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 775                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |



**US3822043**

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**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

| TIMEPOINT                                                                                                                                                                       | DAY 782                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

TIMEPOINT

DAY 796

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

**US3822043**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3822043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3822043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3822043**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822043

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:35

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

**US3822043**

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

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

**Generated On: 26 Nov 2020 09:55:35**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3822043

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:55:35

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US126-2020-MRNA-1273-P30<br>1000006                                                                                                                          |
| Adverse event                                                  | SMALL LYMPHOCYTIC<br>LYMPHOMA                                                                                                                                    |
| 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)                                       | 06 OCT 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       | 11:00 (24 HR)                                                                                                                                                    |
| AE start date and time (derived)                               | 06 OCT 2020 11:00                                                                                                                                                |
| Ongoing?                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         |                                                                                                                                                                  |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |

v6.020 DTW (1102)

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US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Persistent or significant disability or incapacity                           | False                                                                                                                                                                                                                                                                           |
| Congenital anomaly or birth defect                                           | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                              | True                                                                                                                                                                                                                                                                            |
| Relationship to investigational product                                      | Not Related <input type="radio"/><br>Related <input checked="" type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                              | Not Related <input type="radio"/><br>Related <input checked="" type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>                                                                         |
| Other action taken (check all that apply)                                    |                                                                                                                                                                                                                                                                                 |
| None                                                                         | True                                                                                                                                                                                                                                                                            |
| Concomitant Medication                                                       | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input 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: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |



US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

---

THE PATIENT WAS SCHEDULED  
FOR ROUTINE CT OF THE  
CHEST TO SCREEN FOR LUNG  
CANCER ON 9/5/2020. THE CT  
SHOWED AN ENLARGED LET  
AXILLARY LYMPH NODE THAT  
WAS NEW SINCE 6/26/2018. DUE  
TO THE FINDINGS THE SUBJECT  
WAS SCHEDULED FOR AN  
ULTRASOUND GUIDED BIOPSY.  
THE BIOPSY RESULTS WERE  
SMALL LYMPHOCYTIC  
LYMPHOMA.

---

|                                                            |   |
|------------------------------------------------------------|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |
|------------------------------------------------------------|---|

---

|                                                            |   |
|------------------------------------------------------------|---|
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
|------------------------------------------------------------|---|

---

|                                                      |  |
|------------------------------------------------------|--|
| Admitted to ICU Derived (CSA Programming Field Only) |  |
|------------------------------------------------------|--|

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US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | ENLARGED LEFT AXILLARY<br>LYMPH NODES                                                                                                                            |
| 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)                                       | 5 SEP 2020                                                                                                                                                       |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 06 OCT 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| v6.020 DTW (1102)                                              |                                                                                                                                                                  |
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US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Persistent or significant disability or incapacity                           | False                                                                                                                                                                                                                                                                           |
| Congenital anomaly or birth defect                                           | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                              | False                                                                                                                                                                                                                                                                           |
| Relationship to investigational product                                      | Not Related <input type="radio"/><br>Related <input checked="" type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                              | Not Related <input type="radio"/><br>Related <input checked="" type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>                                                                         |
| Other action taken (check all that apply)                                    |                                                                                                                                                                                                                                                                                 |
| None                                                                         | False                                                                                                                                                                                                                                                                           |
| Concomitant Medication                                                       | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                        | True                                                                                                                                                                                                                                                                            |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    | SUBJECT WAS SCHEDULED FOR AN ULTRASOUND GUIDED BIOPSY                                                                                                                                                                                                                           |
| 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)                         |                                                                                                                                                                                                                                                                                 |

US3822043

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

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

**Generated On: 26 Nov 2020 09:55:35**

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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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US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:35

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | AMLODIPINE                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPERTENSION                                                                                                                                                                                                                                                                                                                                                                                                             |
| 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 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"/>                                                                                                                                                                                            |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:35

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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)                                          | 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) <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)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:35

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | SIMVASTATIN                                                                                                                                                                                                                                                                                                                                                                                                              |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | MIXED HYPERLIPIDEMIA                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration              | 20                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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)

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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)                                          | UN                       | UNK 2009                         |
| 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)                                  | 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)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | PROLIA                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | OSTEOPOROSIS                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration        | 60                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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 type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input checked="" type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | EVERY 6 MONTHS<br>Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input checked="" 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"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 2017                         |
| 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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:35

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | IPRATROPIUM BROMIDE                                                                                                                                                                                                                                                                                                                                                                                                      |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | SUPPLEMENT                                                                                                                                                                                                                                                                                                                                                                                                               |
| Dose per administration        | 42                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input type="radio"/><br>ug <input checked="" 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 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 (4)

Generated On: 26 Nov 2020 09:55:35

|                                                    |                          |                                     |
|----------------------------------------------------|--------------------------|-------------------------------------|
|                                                    | Respiratory (Inhalation) | <input type="checkbox"/>            |
|                                                    | Intralesional            | <input type="checkbox"/>            |
|                                                    | Intraperitoneal          | <input type="checkbox"/>            |
|                                                    | Nasal                    | <input checked="" 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 2012              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?                                           | Yes                      | <input checked="" type="checkbox"/> |
|                                                    | No                       | <input type="checkbox"/>            |
| <hr/>                                              |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy) <hr/>       |                          |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|                                                    | No                       | <input checked="" 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 (5)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | SERTRALINE                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | DEPRESSION AND ANXIETY                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 50                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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)

Generated On: 26 Nov 2020 09:55:35

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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)                                          | UN                       | UNK 1997                         |
| 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)                                  | 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)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | LORAZEPAM                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | RESTLESS LEG                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration        | 1                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 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 (6)

Generated On: 26 Nov 2020 09:55:35

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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)                                          | UN                       | UNK 2018                         |
| 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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | OMEPRAZOLE                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | GASTROESOPHAGEAL REFLUX<br>DISEASE                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose per administration        | 40                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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"/>                                                                                                                                                                                                                                   |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intramuscular            | <input type="radio"/>            |
|                                                    | Respiratory (Inhalation) | <input type="radio"/>            |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2012                         |
| 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"/> |
| 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             | ASPIRIN                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | CARDIAC HEALTH                                                                                                                                                                                                                                                                                                                                                                                                           |
| Dose per administration        | 81                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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 (8)

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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)                                          | UN                       | UNK 2011                         |
| 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)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:35

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | VITAMIN D3                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | SUPPLEMENT                                                                                                                                                                                                                                                                                                                                                                                                               |
| Dose per administration        | 1000                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 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 (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 <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 2010                         |
| 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)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | WOMEN'S MULTI VITAMIN                                                                                                                                                                                                                                                                                                                                                                                                    |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | SUPPLEMENT                                                                                                                                                                                                                                                                                                                                                                                                               |
| 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 checked="" 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 (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 <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 2010                         |
| 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)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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|                                |                                             |
|--------------------------------|---------------------------------------------|
| Name of Medication             | CALCIUM                                     |
| Prophylaxis                    | Yes <input checked="" type="radio"/>        |
|                                | No <input type="radio"/>                    |
| Indication                     | SUPPLEMENT                                  |
| Dose per administration        | 600                                         |
| Dose unit                      | mg <input checked="" type="radio"/>         |
|                                | ug <input type="radio"/>                    |
|                                | mL <input type="radio"/>                    |
|                                | g <input type="radio"/>                     |
|                                | IU <input type="radio"/>                    |
|                                | tablet <input type="radio"/>                |
|                                | capsule <input type="radio"/>               |
|                                | puff <input type="radio"/>                  |
|                                | Other <input type="radio"/>                 |
| If dose unit is Other, specify |                                             |
| Frequency                      | once daily <input checked="" type="radio"/> |
|                                | twice daily <input type="radio"/>           |
|                                | three times daily <input type="radio"/>     |
|                                | four times daily <input type="radio"/>      |
|                                | every other day <input type="radio"/>       |
|                                | every week <input type="radio"/>            |
|                                | every month <input type="radio"/>           |
|                                | as needed <input type="radio"/>             |
|                                | once <input type="radio"/>                  |
|                                | unknown <input type="radio"/>               |
|                                | other <input type="radio"/>                 |
| If frequency is Other, specify |                                             |
| Route of administration        | Oral <input checked="" type="radio"/>       |
|                                | Topical <input type="radio"/>               |
|                                | Subcutaneous <input type="radio"/>          |
|                                | Transdermal <input type="radio"/>           |
|                                | Intraocular <input type="radio"/>           |
|                                | 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)                                          | UN UNK 2010              |                                  |
| 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)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | PROBIOTIC                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | SUPPLEMENT                                                                                                                                                                                                                                                                                                                                                                                                               |
| 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 checked="" 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 (12)

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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)                                          | UN                       | UNK 2018                         |
| 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)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Form: Prior/Concomitant Medication and Vaccination (13)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | SHINGRIX                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | VACCINE                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Dose per administration        | UNK                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input checked="" 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 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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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)                                          |                          | 21 FEB 2019                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?                                                          | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 21 FEB 2019                         |
| <hr/>                                                             |                          |                                     |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" 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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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | TRELEGY ELLIPTA                                                                                                                                                                                                                                                                                                                                                                                                          |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ASTHMA                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 100                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input type="radio"/><br>ug <input checked="" 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 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 checked="" type="radio"/> |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2018                         |
| 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)                   | 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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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | ALBUTEROL                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | COPD                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 90                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input type="radio"/><br>ug <input checked="" 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 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 (15)

Generated On: 26 Nov 2020 09:55:35

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Respiratory (Inhalation) | <input checked="" type="radio"/> |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2018                         |
| 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 (16)

Generated On: 26 Nov 2020 09:55:35

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | IPRATROPIUM-ALBUTEROL                                                                                                                                                                                                                                                                                                                                                                                                    |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | COPD                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 3                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 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 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 (16)

Generated On: 26 Nov 2020 09:55:35

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Respiratory (Inhalation) | <input checked="" type="radio"/> |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2018                         |
| 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 (17)

Generated On: 26 Nov 2020 09:55:35

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | BUDESONIDE                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | COPD                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 2                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input checked="" 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 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 (17)

Generated On: 26 Nov 2020 09:55:35

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Respiratory (Inhalation) | <input checked="" type="radio"/> |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2018                         |
| 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 (18)

Generated On: 26 Nov 2020 09:55:35

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | DIPHTHERIA, TETANUS,<br>PERTUSSIS                                                                                                                                                                                                                                                                                                                                                                                        |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | VACCINE                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Dose per administration        | UNK                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input checked="" 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 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"/>                                                                                                                                                                                                                                              |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:35

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intramuscular            | <input checked="" type="radio"/> |
|                                                    | Respiratory (Inhalation) | <input type="radio"/>            |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 01 MAY 2012                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?                                           | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| <hr/>                                              |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 1 MAY 2012                       |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| <hr/>                                              |                          |                                  |
| 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)

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|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | INFLUENZA                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | VACCINE                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Dose per administration              | UNK                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                            | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input checked="" 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 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: 26 Nov 2020 09:55:35

|                                                    |                          |                                     |
|----------------------------------------------------|--------------------------|-------------------------------------|
|                                                    | 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)                           |                          | 20 OCT 2018                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?                                           | Yes                      | <input type="checkbox"/>            |
|                                                    | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                              |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 20 OCT 2018                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|                                                    | No                       | <input checked="" 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 (20)

Generated On: 26 Nov 2020 09:55:35

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | PNEUMOCOCCAL                                                                                                                                                                                                                                                                                                                                                                                                             |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | VACCINE                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Dose per administration        | UNK                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input checked="" 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 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 (20)

Generated On: 26 Nov 2020 09:55:35

|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | 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)                                          |                          | 09 FEB 2016                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?                                                          | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 9 FEB 2016                          |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" 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 Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:55:35

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:55:35

| Procedure/Surgery date (dd MMM<br>yyyy) | Procedure/Surgery                                                                                                                                         | Indication      | If indication is Other, specify |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------------------------------|
| 05 SEP 2020                             | CT CHEST FOR LUNG CANCER<br>SCREENING - MODERATE<br>CENTRIOBULAR EMPHYSEMA,<br>MODERATE-SEVERE CORONARY<br>ARTERIAL CALCIFICATIONS.<br>NORMAL HEART SIZE. | Medical History |                                 |
| 02 OCT 2020                             | ULTRASOUNDS GUIDED CORE<br>BIOPSY                                                                                                                         | Adverse Event   |                                 |

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:55:35

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:55:35

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐



US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

|                                                                |                                                               |
|----------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                          | USA-US126-2020-MRNA-1273-P301000006                           |
| Serious                                                        | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                          | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                               | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name                                      | CHRISTINA                                                     |
| Investigator's Last Name                                       | KENNELLY                                                      |
| Site Address: Street                                           |                                                               |
| Site Address: City                                             |                                                               |
| Site Address: State                                            |                                                               |
| Site Address: Postal Code                                      |                                                               |
| Investigator Country                                           | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                             | 4                                                             |

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Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:55:35

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US126-2020-MRNA-1273-P301000006                              |
| 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 type="radio"/><br>No <input checked="" 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 checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | CHRISTINA                                                        |
| Investigator's Last Name                                                                                                                                                                      | KENNELLY                                                         |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 26/OCT/2020 21:07                                                |
| 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                                                             |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:55:35

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US126-2020-MRNA-1273-P301000006                              |
| 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 type="radio"/><br>No <input checked="" 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 checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | CHRISTINA                                                        |
| Investigator's Last Name                                                                                                                                                                      | KENNELLY                                                         |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 28/OCT/2020 13:46                                                |
| 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                                                             |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:55:35

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US126-2020-MRNA-1273-P301000006                              |
| 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 type="radio"/><br>No <input checked="" 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 checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | CHRISTINA                                                        |
| Investigator's Last Name                                                                                                                                                                      | KENNELLY                                                         |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 19/NOV/2020 14:28                                                |
| 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                                                             |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:55:35

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US126-2020-MRNA-1273-P301000006                              |
| 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 type="radio"/><br>No <input checked="" 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 checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | CHRISTINA                                                        |
| Investigator's Last Name                                                                                                                                                                      | KENNELLY                                                         |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 24/NOV/2020 19:28                                                |
| 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

US3822043 (Prod: Tryon Medical Partners, PLLC)

**US3822043**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:55:35**

[Participant ID](#)

| Audit                    | User                             | Time (GMT)           |
|--------------------------|----------------------------------|----------------------|
| DataPoint Un-verified.   | (b) (4), (b) (6)                 | 04 Nov 2020 18:51:25 |
| DataPoint Verified.      | (b) (4), (b) (6)                 | 22 Oct 2020 15:49:26 |
| User entered 'US3822043' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 07 Aug 2020 17:14:34 |

US3822043

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

[Was this visit performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:19 |



US3822043

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                                           | Time (GMT)           |
|----------------------------|------------------------------------------------|----------------------|
| User entered '07 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 07 Aug 2020 17:14:35 |

US3822043

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:55:35**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:19 |

**US3822043**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:55:35**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 07 Aug 2020 18:12:19 |

US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

Date of Birth (MMM yyyy)

| Audit                      | User                                           | Time (GMT)           |
|----------------------------|------------------------------------------------|----------------------|
| User entered (b) (6) 1944' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 07 Aug 2020 17:14:35 |

US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

[Age](#)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '75' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |

**US3822043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:55:35**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 07 Aug 2020 18:12:40 |

**US3822043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:55:35**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '75' | System | 07 Aug 2020 18:13:01 |

US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

Sex

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User entered 'Female (F)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |



US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

[Ethnicity](#)

| Audit                                                          | User                             | Time (GMT)           |
|----------------------------------------------------------------|----------------------------------|----------------------|
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |

US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

White

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '1' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |

US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

[Black](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |

US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

[Asian](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |

US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

[American Indian or Alaska Native](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |

US3822043

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:55:35**

[Native Hawaiian or other Pacific Islander](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |

US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

[Other](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |

US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

[If race is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |



US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

Unknown

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |

US3822043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:35

[Not reported](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:12:40 |

US3822043

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:55:35**

[Date of Informed Consent \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '07 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:13:01 |

US3822043

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:55:35**

[Month and Year of Informed Consent \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 07 Aug 2020 18:13:01 |

**US3822043**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:55:35**

[Year of Informed Consent \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 07 Aug 2020 18:13:01 |

US3822043

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:55:35**

[Protocol Version](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| User entered 'Amendment 1 (1)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:13:01 |

US3822043

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:35

[Was participant enrolled in the study?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:13:01 |

US3822043

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:55:35**

[If No, indicate reason for screen fail](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:13:01 |



US3822043

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:55:35**

If reason for screen fail is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:13:01 |

US3822043

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:55:35**

[Was this participant screened previously?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:13:01 |

US3822043

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:35

[If Yes, previous participant number](#)

| Audit               | User                                           | Time (GMT)           |
|---------------------|------------------------------------------------|----------------------|
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 07 Aug 2020 17:14:35 |

US3822043

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:55:35**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 18:13:06 |

US3822043

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 09:55:35**

[Did the participant meet all eligibility criteria?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:13:06 |

US3822043

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:55:35

[Were any significant conditions reported?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 18 Nov 2020 14:35:07 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:28:46 |

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                             | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.<br>' (Site from DM).             | (b) (4), (b) (6)                 | 13 Oct 2020 12:39:43 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.<br>' answered with 'updated' (Site from DM). | (b) (4), (b) (6)                 | 06 Oct 2020 16:46:55 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.<br>' (Site from DM).             | (b) (4), (b) (6)                 | 28 Sep 2020 09:49:25 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive lung disease - version MedDRA\23.0.                             | Coder Import (b) (4)<br>(b) (4)  | 20 Aug 2020 22:30:22 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                       | Coder Import (b) (4)             | 20 Aug 2020 22:30:22 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                     | System                           | 20 Aug 2020 22:29:28 |
| User entered 'Chronic Obstructive Lung Disease'                                                                                                                                                                                                                                                   | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:29:14 |

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '06 Nov 2018' | Kelly Woodell (b) (4) | 20 Aug 2020 22:29:14 |
|                            | (b) (4)               |                      |



US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:29:14 |

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:35

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:29:14 |

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:35

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:29:14 |

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:29:14 |

**US3822043**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Nov 2018' | System | 20 Aug 2020 22:29:14 |

**US3822043**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 20 Aug 2020 22:29:14 |

**US3822043**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:29:14 |

**US3822043**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:29:14 |



US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                  | User                             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastrooesophageal reflux disease - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 20 Aug 2020 22:31:23 |
| 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 Aug 2020 22:31:23 |
| Data point term sent to Coder                                                                                                                                                                                                                                                          | System                           | 20 Aug 2020 22:30:29 |
| User entered 'Gastrooesophageal reflux disease'                                                                                                                                                                                                                                        | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:29:43 |

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered '06 Nov 2018' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:29:43 |

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:29:43 |
|                     | (b) (4)               |                      |

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:35

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:29:43 |

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:35

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered empty. | Kelly Woodell (b) (4) | 20 Aug 2020 22:29:43 |
|                     | (b) (4)               |                      |

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:29:43 |

**US3822043**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Nov 2018' | System | 20 Aug 2020 22:29:43 |

**US3822043**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 20 Aug 2020 22:29:43 |



US3822043

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:29:43 |

**US3822043**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:29:43 |

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                                        | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                          | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Mixed anxiety and depressive disorder, LLT: Mixed anxiety and depressive disorder - version MedDRA\23.0. | Coder Import (b) (4)  | 20 Aug 2020 22:31:23 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                  | (b) (4)               | 20 Aug 2020 22:31:23 |
| Data point term sent to Coder                                                                                                                                                                                                                | System                | 20 Aug 2020 22:30:30 |
| User entered 'Mixed anxiety and depressive disorder'                                                                                                                                                                                         | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:11 |
|                                                                                                                                                                                                                                              | (b) (4)               |                      |

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered '06 Nov 2018' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:30:11 |

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:11 |

**US3822043**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Condition ongoing at study entry](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:11 |

**US3822043**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:55:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:30:11 |

**US3822043**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:11 |



**US3822043**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Nov 2018' | System | 20 Aug 2020 22:30:11 |

**US3822043**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 20 Aug 2020 22:30:11 |

US3822043

**Folder:** Screening

**Form:** Medical History (3)

**Generated On:** 26 Nov 2020 09:55:35

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:30:11 |

**US3822043**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:30:11 |

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                             | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.<br>' (Site from DM).             | (b) (4), (b) (6)                 | 13 Oct 2020 12:39:55 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.<br>' answered with 'updated' (Site from DM). | (b) (4), (b) (6)                 | 06 Oct 2020 16:47:17 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.<br>' (Site from DM).             | (b) (4), (b) (6)                 | 28 Sep 2020 09:49:34 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.                                                                                                     | Coder Import (b) (4)<br>(b) (4)  | 20 Aug 2020 22:31:23 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                       | Coder Import (b) (4)             | 20 Aug 2020 22:31:23 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                     | System                           | 20 Aug 2020 22:30:30 |
| User entered 'Hypertension'                                                                                                                                                                                                                                                                       | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:30:29 |

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered 'UN UNK 2015' | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:29 |

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:29 |

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:35

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:30:29 |



US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:35

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered empty. | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:29 |
|                     | (b) (4)               |                      |

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:29 |

**US3822043**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2015' | System | 20 Aug 2020 22:30:29 |

**US3822043**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2015' | System | 20 Aug 2020 22:30:29 |

**US3822043**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:30:29 |

**US3822043**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:30:29 |

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                                                 | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                   | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Metabolic and nutritional disorders congenital, HLT: Inborn errors of lipid metabolism, PT: Type V hyperlipidaemia, LLT: Mixed hyperlipidemia - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 20 Aug 2020 22:32:24 |
| 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 Aug 2020 22:32:24 |
| Data point term sent to Coder                                                                                                                                                                                                                         | System                           | 20 Aug 2020 22:31:31 |
| User entered 'Mixed Hyperlipidemia'                                                                                                                                                                                                                   | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:30:52 |

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered '06 Nov 2018' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:30:52 |



**US3822043**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:52 |

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:35

[Condition ongoing at study entry](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:52 |

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:35

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered empty. | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:52 |
|                     | (b) (4)               |                      |

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:30:52 |

US3822043

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Nov 2018' | System | 20 Aug 2020 22:30:52 |

**US3822043**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 20 Aug 2020 22:30:52 |

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:55:35

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:30:52 |

**US3822043**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:30:52 |



US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                           | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                             | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0. | Coder Import (b) (4)  | 20 Aug 2020 22:32:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                    | (b) (4)               | 20 Aug 2020 22:32:24 |
| Data point term sent to Coder                                                                                                                                                                                                   | System                | 20 Aug 2020 22:31:32 |
| User entered 'Osteoporosis'                                                                                                                                                                                                     | Kelly Woodell (b) (4) | 20 Aug 2020 22:31:12 |
|                                                                                                                                                                                                                                 | (b) (4)               |                      |

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '06 Nov 2018' | Kelly Woodell (b) (4) | 20 Aug 2020 22:31:12 |
|                            | (b) (4)               |                      |

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:31:12 |

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:35

[Condition ongoing at study entry](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4) | 20 Aug 2020 22:31:12 |
|                        | (b) (4)               |                      |

**US3822043**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:55:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered empty. | Kelly Woodell (b) (4) | 20 Aug 2020 22:31:12 |
|                     | (b) (4)               |                      |

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:31:12 |

**US3822043**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Nov 2018' | System | 20 Aug 2020 22:31:12 |

**US3822043**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 20 Aug 2020 22:31:12 |



**US3822043**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:31:12 |

**US3822043**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:31:12 |

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                    | User                             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                      | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 20 Aug 2020 22:33:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                             | Coder Import (b) (4)<br>(b) (4)  | 20 Aug 2020 22:33:25 |
| Data point term sent to Coder                                                                                                                                                                            | System                           | 20 Aug 2020 22:32:32 |
| User entered 'Restless leg syndrome'                                                                                                                                                                     | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:31:42 |

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered '06 Nov 2018' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:31:42 |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:31:42 |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:35

[Condition ongoing at study entry](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4) | 20 Aug 2020 22:31:42 |

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:35

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered empty. | Kelly Woodell (b) (4) | 20 Aug 2020 22:31:42 |
|                     | (b) (4)               |                      |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:31:42 |



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**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Nov 2018' | System | 20 Aug 2020 22:31:42 |

**US3822043**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 20 Aug 2020 22:31:42 |

US3822043

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:31:42 |

**US3822043**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:31:42 |

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                   | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                     | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 20 Aug 2020 22:33:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                            | Coder Import (b) (4)<br>(b) (4)  | 20 Aug 2020 22:33:25 |
| Data point term sent to Coder                                                                                                                                           | System                           | 20 Aug 2020 22:32:32 |
| User entered 'Diverticulosis'                                                                                                                                           | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:32:18 |

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered '06 Nov 2018' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:32:18 |

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:32:18 |

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:35

[Condition ongoing at study entry](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4) | 20 Aug 2020 22:32:18 |



US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:35

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:32:18 |

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 20 Aug 2020 22:32:18 |

**US3822043**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Nov 2018' | System | 20 Aug 2020 22:32:18 |

**US3822043**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 20 Aug 2020 22:32:18 |

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:55:35

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:32:18 |

**US3822043**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 22:32:18 |

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                 | User                            | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                   | (b) (4), (b) (6)                | 10 Nov 2020 19:56:39 |
| User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 20 Oct 2020 15:09:39 |
| 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 Oct 2020 15:09:39 |
| Data point term sent to Coder                                                                                                                                         | System                          | 20 Oct 2020 15:09:23 |
| User entered 'Post menopausal'                                                                                                                                        | (b) (4), (b) (6)                | 20 Oct 2020 15:09:16 |

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 10 Nov 2020 19:56:39 |
| User entered 'un UNK 1969' | (b) (4), (b) (6) | 20 Oct 2020 15:09:16 |



US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 19:56:39 |
| User entered '0'    | (b) (4), (b) (6) | 20 Oct 2020 15:09:16 |

**US3822043**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 10 Nov 2020 19:56:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Oct 2020 15:09:16 |

**US3822043**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:55:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 19:56:39 |
| User entered empty. | (b) (4), (b) (6) | 20 Oct 2020 15:09:16 |

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:35

Stop date completely unknown

| Audit                                                                                                                                                                                                                                                                               | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per Hem/Onc records 21OCT2020, per past HM on page 4 of 16, subject is noted as having Stage IV NSCLC, bone mets, Stage IIA invasive mammary carcinoma R breast, bioprosthetic mitral valve porcine. Kindly confirm if these should ' (Site from CRA).           | (b) (4), (b) (6)      | 18 Nov 2020 14:39:19 |
| Query 'Per Hem/Onc records 21OCT2020, per past HM on page 4 of 16, subject is noted as having Stage IV NSCLC, bone mets, Stage IIA invasive mammary carcinoma R breast, bioprosthetic mitral valve porcine. Kindly confirm if these should ' answered with 'added' (Site from CRA). | Kelly Woodell (b) (4) | 10 Nov 2020 19:58:04 |
| DataPoint Verified.                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User closed query 'Per source subject is noted as having a history of Pre melanoma left forearm, kindly consider adding to EDC.' (Site from CRA).                                                                                                                                   | (b) (4), (b) (6)      | 10 Nov 2020 19:56:13 |
| User closed query 'Per Hem/Onc source note dated 21OCT2020, subject has history of a pulmonary nodule. Kindly consider adding to EDC. ' (Site from CRA).                                                                                                                            | (b) (4), (b) (6)      | 10 Nov 2020 19:56:03 |
| User closed query 'Per source subject is noted as having history of Basil cell carcinoma on nose. Kindly consider adding to EDC. ' (Site from CRA).                                                                                                                                 | (b) (4), (b) (6)      | 10 Nov 2020 19:55:56 |
| Query 'Per Hem/Onc source note dated 21OCT2020, subject has history of a pulmonary nodule. Kindly consider adding to EDC. ' answered with 'added' (Site from CRA).                                                                                                                  | Kelly Woodell (b) (4) | 10 Nov 2020 19:52:52 |
| Query 'Per source subject is noted as having a history of Pre melanoma left forearm, kindly consider adding to EDC.' answered with 'added' (Site from CRA).                                                                                                                         | Kelly Woodell (b) (4) | 10 Nov 2020 19:52:40 |
| Query 'Per source subject is noted as having history of Basil cell carcinoma on nose. Kindly consider adding to EDC. ' answered with 'added' (Site from CRA).                                                                                                                       | Kelly Woodell (b) (4) | 10 Nov 2020 19:52:35 |
| User opened query 'Per Hem/Onc records 21OCT2020, per past HM on page 4 of 16, subject is noted as having Stage IV NSCLC, bone mets, Stage IIA invasive mammary carcinoma R breast, bioprosthetic mitral valve porcine. Kindly confirm if these should ' (Site from CRA).           | (b) (4), (b) (6)      | 04 Nov 2020 21:20:18 |

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit                                                                                                                                                        | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'Per Hem/Onc source note dated 21OCT2020, subject has history of a pulmonary nodule. Kindly consider adding to EDC. ' (Site from CRA).     | (b) (4), (b) (6) | 04 Nov 2020 21:09:09 |
| User opened query 'Per source subject is noted as having a history of Pre melanoma left forearm, kindly consider adding to EDC.' (Site from CRA).            | (b) (4), (b) (6) | 04 Nov 2020 20:36:02 |
| User opened query 'Per source subject is noted as having history of Basil cell carcinoma on nose. Kindly consider consider adding to EDC. ' (Site from CRA). | (b) (4), (b) (6) | 04 Nov 2020 20:34:32 |
| User entered '0'                                                                                                                                             | (b) (4), (b) (6) | 20 Oct 2020 15:09:16 |

**US3822043**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1969' | System | 20 Oct 2020 15:09:16 |

**US3822043**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1969' | System | 20 Oct 2020 15:09:16 |

US3822043

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Oct 2020 15:09:16 |



**US3822043**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Oct 2020 15:09:16 |

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                         | User                             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                           | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 10 Nov 2020 19:54:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                                                                  | Coder Import (b) (4)<br>(b) (4)  | 10 Nov 2020 19:54:46 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                 | System                           | 10 Nov 2020 19:53:45 |
| User entered 'Basal cell carcinoma'                                                                                                                                                                                                                                                           | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 19:53:12 |

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered 'un UNK 2015' | Kelly Woodell (b) (4) | 10 Nov 2020 19:53:12 |

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 10 Nov 2020 19:53:12 |

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:35

[Condition ongoing at study entry](#)

| Audit                                                                                                                                                        | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                          | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System). | System                           | 10 Nov 2020 19:53:22 |
| User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System). | System                           | 10 Nov 2020 19:53:12 |
| User entered 'No (N)'                                                                                                                                        | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 19:53:12 |

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:35

If No, please specify the stop date (dd MMM yyyy)

| Audit                                                             | User                             | Time (GMT)           |
|-------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                               | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| User entered 'un UNK 2015' reason for change:<br>Data Entry Error | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 19:53:22 |
| User entered empty.                                               | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 19:53:12 |

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 10 Nov 2020 19:53:12 |

**US3822043**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2015' | System | 10 Nov 2020 19:53:12 |



**US3822043**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2015' | System | 10 Nov 2020 19:53:12 |

**US3822043**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2015' | System | 10 Nov 2020 19:53:22 |
| User entered empty.     | System | 10 Nov 2020 19:53:12 |

**US3822043**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2015' | System | 10 Nov 2020 19:53:22 |
| User entered empty. | System | 10 Nov 2020 19:53:12 |

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                                       | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Cutaneous neoplasms benign, HLT: Skin neoplasms benign, PT: Juvenile melanoma benign, LLT: Benign melanoma - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 11 Nov 2020 06:56:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                     | Coder Import (b) (4)<br>(b) (4)  | 11 Nov 2020 06:56:47 |
| DataPoint Verified.                                                                                                                                                                                                                         | (b) (4), (b) (6)                 | 10 Nov 2020 19:56:39 |
| Data point term sent to Coder                                                                                                                                                                                                               | System                           | 10 Nov 2020 19:54:46 |
| User entered 'Pre melanoma left forearm'                                                                                                                                                                                                    | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 19:53:47 |

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered 'un UNK 2014' | Kelly Woodell (b) (4) | 10 Nov 2020 19:53:47 |
|                            | (b) (4)               |                      |

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 10 Nov 2020 19:53:47 |

**US3822043**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Condition ongoing at study entry](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered 'No (N)' | Kelly Woodell (b) (4) | 10 Nov 2020 19:53:47 |
|                       | (b) (4)               |                      |

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:35

If No, please specify the stop date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered 'un UNK 2014' | Kelly Woodell (b) (4) | 10 Nov 2020 19:53:47 |
|                            | (b) (4)               |                      |



US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 10 Nov 2020 19:56:39 |
| User entered '0'    | Kelly Woodell (b) (4) | 10 Nov 2020 19:53:47 |

US3822043

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 10 Nov 2020 19:53:47 |

**US3822043**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2014' | System | 10 Nov 2020 19:53:47 |

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:55:35

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 10 Nov 2020 19:53:47 |

**US3822043**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2014' | System | 10 Nov 2020 19:53:47 |

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                     | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)                 | 18 Nov 2020 14:36:12 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Non-small cell neoplasms malignant of the respiratory tract cell type specified, PT: Non-small cell lung cancer stage IV, LLT: Non-small cell lung cancer stage IV - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 11 Nov 2020 07:03:58 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                                                                                                                                                   | Coder Import (b) (4)<br>(b) (4)  | 11 Nov 2020 07:03:58 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                                             | System                           | 10 Nov 2020 19:58:54 |
| User entered 'Stage IV non small cell lung cancer'                                                                                                                                                                                                                                                                                                                        | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 19:58:33 |

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:36:14 |
| User entered empty. | Kelly Woodell (b) (4) | 10 Nov 2020 19:58:33 |

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:36:16 |
| User entered '1'    | Kelly Woodell (b) (4) | 10 Nov 2020 19:58:33 |



**US3822043**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Condition ongoing at study entry](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 18 Nov 2020 14:36:19 |
| User entered 'No (N)' | Kelly Woodell (b) (4) | 10 Nov 2020 19:58:33 |

**US3822043**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:55:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 18 Nov 2020 14:36:21 |
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 19:58:33 |

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:36:23 |
| User entered '1'    | Kelly Woodell (b) (4) | 10 Nov 2020 19:58:33 |

**US3822043**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 19:58:33 |

**US3822043**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 19:58:33 |

**US3822043**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 19:58:33 |

**US3822043**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 19:58:33 |

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                             | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Un-verified.                                                                                                                                                                                            | (b) (4), (b) (6)                 | 18 Nov 2020 14:36:46 |
| DataPoint Verified.                                                                                                                                                                                               | (b) (4), (b) (6)                 | 18 Nov 2020 14:36:37 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung nodule - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)  | 10 Nov 2020 20:01:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                       | Coder Import (b) (4)<br>(b) (4)  | 10 Nov 2020 20:01:45 |
| Data point term sent to Coder                                                                                                                                                                                     | System                           | 10 Nov 2020 20:01:00 |
| User entered 'Lung nodule'                                                                                                                                                                                        | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:00:05 |



**US3822043**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Un-verified.     | (b) (4), (b) (6)                 | 18 Nov 2020 14:36:48 |
| DataPoint Verified.        | (b) (4), (b) (6)                 | 18 Nov 2020 14:36:40 |
| User entered '05 Feb 2014' | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:00:05 |

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:00:05 |

US3822043

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:00:05 |

US3822043

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:55:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:00:05 |

US3822043

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop date completely unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:00:05 |

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:55:35

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Feb 2014' | System | 10 Nov 2020 20:00:05 |

**US3822043**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2014' | System | 10 Nov 2020 20:00:05 |

**US3822043**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:00:05 |



**US3822043**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:00:05 |

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                         | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                           | (b) (4), (b) (6)                 | 18 Nov 2020 14:36:53 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Metastases, HLT: Metastases to specified sites, PT: Metastases to bone, LLT: Bone metastases - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 10 Nov 2020 21:54:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                       | Coder Import (b) (4)<br>(b) (4)  | 10 Nov 2020 21:54:40 |
| Data point term sent to Coder                                                                                                                                                                                                 | System                           | 10 Nov 2020 20:01:00 |
| User entered 'Bone Metastasis'                                                                                                                                                                                                | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:00:30 |

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 18 Nov 2020 14:36:55 |
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:00:30 |

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:36:59 |
| User entered '1'    | Kelly Woodell (b) (4) | 10 Nov 2020 20:00:30 |

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:55:35

[Condition ongoing at study entry](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 18 Nov 2020 14:37:02 |
| User entered 'No (N)' | Kelly Woodell (b) (4) | 10 Nov 2020 20:00:30 |
|                       | (b) (4)               |                      |

**US3822043**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:55:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:37:05 |
| User entered empty. | Kelly Woodell (b) (4) | 10 Nov 2020 20:00:30 |

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:37:06 |
| User entered '1'    | Kelly Woodell (b) (4) | 10 Nov 2020 20:00:30 |

**US3822043**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:00:30 |



**US3822043**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:00:30 |

**US3822043**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:00:30 |

**US3822043**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:00:30 |

US3822043

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                                | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6)                 | 18 Nov 2020 14:38:08 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Invasive breast carcinoma, LLT: Invasive breast carcinoma - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 11 Nov 2020 07:03:57 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                                                                              | Coder Import (b) (4)<br>(b) (4)  | 11 Nov 2020 07:03:57 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                        | System                           | 10 Nov 2020 20:06:06 |
| User entered 'Stage IIA invasive mammary carcinoma'                                                                                                                                                                                                                                                  | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:05:34 |

US3822043

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 18 Nov 2020 14:38:10 |
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:05:34 |

US3822043

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:38:13 |
| User entered '1'    | Kelly Woodell (b) (4) | 10 Nov 2020 20:05:34 |

US3822043

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:55:35

[Condition ongoing at study entry](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 18 Nov 2020 14:38:15 |
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:05:34 |

**US3822043**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:55:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 18 Nov 2020 14:38:17 |
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:05:34 |



US3822043

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:38:18 |
| User entered '1'    | Kelly Woodell (b) (4) | 10 Nov 2020 20:05:34 |

**US3822043**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:05:34 |

**US3822043**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:05:34 |

**US3822043**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:05:34 |

**US3822043**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:05:34 |

US3822043

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:55:35

[Condition](#)

| Audit                                                                                                                                                                                                                               | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                 | (b) (4), (b) (6)                 | 18 Nov 2020 14:38:30 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Mitral valve replacement, LLT: Mitral valve replacement - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 10 Nov 2020 21:53:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                             | Coder Import (b) (4)<br>(b) (4)  | 10 Nov 2020 21:53:49 |
| Data point term sent to Coder                                                                                                                                                                                                       | System                           | 10 Nov 2020 20:06:06 |
| User entered 'Bioprosthetic mitral valve (porcine)'                                                                                                                                                                                 | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:06:00 |

US3822043

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:38:32 |
| User entered empty. | Kelly Woodell (b) (4) | 10 Nov 2020 20:06:00 |

US3822043

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:55:35

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:38:35 |
| User entered '1'    | Kelly Woodell (b) (4) | 10 Nov 2020 20:06:00 |



**US3822043**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Condition ongoing at study entry](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 18 Nov 2020 14:38:37 |
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:06:00 |

**US3822043**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:55:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 18 Nov 2020 14:38:39 |
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 20:06:00 |

US3822043

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:55:35

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:38:40 |
| User entered '1'    | Kelly Woodell (b) (4) | 10 Nov 2020 20:06:00 |

**US3822043**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:06:00 |

**US3822043**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:06:00 |

**US3822043**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:06:00 |

**US3822043**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 20:06:00 |

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[Were vital signs assessed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:34:11 |



US3822043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '07 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:34:11 |

US3822043

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:55:35**

**Time of assessment (00:00-23:59)**

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '13:16' | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:34:11 |

**US3822043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:55:35**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 13:16' | System | 20 Aug 2020 22:34:11 |

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[Height \(xxx.x\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User entered '60.5' in    | Kelly Woodell (b) (4) | 20 Aug 2020 22:34:11 |
| DataPoint set to visible. | (b) (4)<br>System     | 07 Aug 2020 18:13:06 |

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[Weight \(xxx.x\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User entered '133' lb     | Kelly Woodell (b) (4) | 20 Aug 2020 22:34:11 |
| DataPoint set to visible. | (b) (4)<br>System     | 07 Aug 2020 18:13:06 |

**US3822043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:55:35**

**BMI (xxx.x)**

| Audit                                      | User   | Time (GMT)           |
|--------------------------------------------|--------|----------------------|
| Amendment Manager: User entered '25.60064' | System | 16 Sep 2020 23:47:36 |
| User entered '25.6'                        | System | 20 Aug 2020 22:34:11 |
| DataPoint set to visible.                  | System | 07 Aug 2020 18:13:06 |

**US3822043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:55:35**

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 20 Aug 2020 22:34:11 |
| DataPoint set to visible. | System | 07 Aug 2020 18:13:06 |

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

Temperature (xxx.x)

| Audit                                                                          | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------|----------------------------------|----------------------|
| User entered missing code ND - Not Done; reason for<br>change Data Entry Error | Krishna Shah (b) (4)<br>(b) (4)  | 29 Oct 2020 19:49:14 |
| User entered '98.2' F                                                          | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:34:11 |



**US3822043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:55:35**

[Route of measurement](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Krishna Shah (b) (4)  | 29 Oct 2020 19:49:14 |
| User entered 'Oral (Oral)'                             | Kelly Woodell (b) (4) | 20 Aug 2020 22:34:11 |

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[If Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:34:11 |

**US3822043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:55:35**

[Pulse \(xxx\)](#)

| Audit                                                                          | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------|----------------------------------|----------------------|
| User entered missing code ND - Not Done; reason for<br>change Data Entry Error | Krishna Shah (b) (4)<br>(b) (4)  | 29 Oct 2020 19:49:14 |
| User entered '78'                                                              | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:34:11 |

**US3822043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:55:35**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 20 Aug 2020 22:34:11 |

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate \(xxx\)](#)

| Audit                                                                          | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------|----------------------------------|----------------------|
| User entered missing code ND - Not Done; reason for<br>change Data Entry Error | Krishna Shah (b) (4)<br>(b) (4)  | 29 Oct 2020 19:49:14 |
| User entered '20'                                                              | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:34:11 |

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 20 Aug 2020 22:34:11 |

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

Systolic Blood Pressure (xxx)

| Audit                                                                          | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------|----------------------------------|----------------------|
| User entered missing code ND - Not Done; reason for<br>change Data Entry Error | Krishna Shah (b) (4)<br>(b) (4)  | 29 Oct 2020 19:49:14 |
| User entered '110'                                                             | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:34:11 |

US3822043

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:55:35**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 22:34:11 |



US3822043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

Diastolic Blood Pressure (xxx)

| Audit                                                                          | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------|----------------------------------|----------------------|
| User entered missing code ND - Not Done; reason for<br>change Data Entry Error | Krishna Shah (b) (4)<br>(b) (4)  | 29 Oct 2020 19:49:14 |
| User entered '70'                                                              | Kelly Woodell (b) (4)<br>(b) (4) | 20 Aug 2020 22:34:11 |

US3822043

**Folder:** Screening

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 09:55:35

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 22:34:11 |

US3822043

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:55:35**

[Was the physical examination performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:24:04 |

US3822043

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:35

Date of examination (dd MMM yyyy)

| Audit                                                                                                                                    | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).    | (b) (4), (b) (6)      | 07 Sep 2020 12:11:30 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). |                       | 02 Sep 2020 18:34:32 |
| User entered '07 Aug 2020'                                                                                                               | Kelly Woodell (b) (4) | 21 Aug 2020 00:24:04 |

US3822043

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:55:35**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '07 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:06 |

US3822043

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:35

Is the participant of childbearing potential?

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:06 |

US3822043

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:35

If No, what is the reason?

| Audit                                                                                                                                                                          | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).             | (b) (4), (b) (6)      | 30 Oct 2020 10:04:58 |
| Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6)      | 20 Oct 2020 15:09:32 |
| User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).             | (b) (4), (b) (6)      | 30 Sep 2020 06:40:18 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)'                                                                                                                               | Kelly Woodell (b) (4) | 21 Aug 2020 00:25:06 |

US3822043

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:55:35**

[If Partner medically sterile or Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:06 |



US3822043

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:55:35**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:06 |

US3822043

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:55:35**

[Date of surgery unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:06 |

US3822043

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:55:35**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'UN UNK 1969' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:06 |

US3822043

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:55:35**

[Date of last menstruation unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:06 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |



US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

[Other](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |



US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

[Specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

No Risk Identified

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '1' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

[Resides in a single family home](#) (i.e., detached housing)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

[Other](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |



US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:35

[Specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:25:39 |

US3822043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

[Was this visit performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:13:35 |

US3822043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '07 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:13:35 |

US3822043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:13:35 |

**US3822043**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:55:35**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 07 Aug 2020 18:13:35 |

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:35

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

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '07 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 07 Aug 2020 17:14:36 |

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:35

What was the participant's randomization number?

| Audit                                                                                                      | User                                           | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System                                         | 21 Aug 2020 02:54:30 |
| Amendment Manager: Data point set to conformant.                                                           | System                                         | 21 Aug 2020 02:54:30 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).                    | System                                         | 07 Aug 2020 17:14:36 |
| User entered '185196' (non-conformant).                                                                    | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 07 Aug 2020 17:14:36 |

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:35

[In what Cohort was the participant enrolled?](#)

| Audit                         | User                                            | Time (GMT)           |
|-------------------------------|-------------------------------------------------|----------------------|
| User entered '>=65 years (3)' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 07 Aug 2020 17:14:36 |



US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:35

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:14:25 |

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:35

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:14:25 |

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:35

Severe obesity (body mass index > or = 40kg/m2

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:14:25 |

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:35

Diabetes (Type I, Type 2, or gestational)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:14:25 |

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:35

[Liver Disease](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:14:25 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:35

Height

| Audit                                                                                                                                                                                                                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).        | (b) (4), (b) (6)                 | 27 Oct 2020 11:21:39 |
| Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'ND' (Site from DM). | (b) (4), (b) (6)                 | 20 Oct 2020 15:09:58 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                                | (b) (4), (b) (6)                 | 20 Oct 2020 15:09:50 |
| User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).        | (b) (4), (b) (6)                 | 16 Oct 2020 14:09:57 |
| User entered '60.5' in                                                                                                                                                                                                                                     | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:35

Weight

| Audit                                                                       | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------|-----------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)      | 20 Oct 2020 15:09:50 |
| User entered '133' lb                                                       | Kelly Woodell (b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:35

Height

| Audit                                                                                                                                                                                                                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).        | (b) (4), (b) (6)                 | 27 Oct 2020 11:21:39 |
| Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'ND' (Site from DM). | (b) (4), (b) (6)                 | 20 Oct 2020 15:09:58 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                                | (b) (4), (b) (6)                 | 20 Oct 2020 15:09:50 |
| User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).        | (b) (4), (b) (6)                 | 16 Oct 2020 14:09:57 |
| User entered '60.5' in                                                                                                                                                                                                                                     | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |



US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:35

Weight

| Audit                                                                       | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------|-----------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)      | 20 Oct 2020 15:09:50 |
| User entered '133' lb                                                       | Kelly Woodell (b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Timepoint](#)

| Audit                                            | User                             | Time (GMT)           |
|--------------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Were vital signs assessed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '07 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

Time of assessment (00:00-23:59)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '13:16' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 13:16' | System | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

Temperature (xxx.x)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered '98.2' F | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |



US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[If Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Pulse \(xxx\)](#)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '78' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate \(xxx\)](#)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '20' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

Systolic Blood Pressure (xxx)

| Audit              | User                             | Time (GMT)           |
|--------------------|----------------------------------|----------------------|
| User entered '110' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

Diastolic Blood Pressure (xxx)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '70' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |



US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:35

Height

| Audit                                                                                                                                                                                                                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).        | (b) (4), (b) (6)                 | 27 Oct 2020 11:21:39 |
| Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'ND' (Site from DM). | (b) (4), (b) (6)                 | 20 Oct 2020 15:09:58 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                                | (b) (4), (b) (6)                 | 20 Oct 2020 15:09:50 |
| User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).        | (b) (4), (b) (6)                 | 16 Oct 2020 14:09:57 |
| User entered '60.5' in                                                                                                                                                                                                                                     | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:35

Weight

| Audit                                                                       | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------|-----------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)      | 20 Oct 2020 15:09:50 |
| User entered '133' lb                                                       | Kelly Woodell (b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Timepoint](#)

| Audit                                              | User                             | Time (GMT)           |
|----------------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Were vital signs assessed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '07 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

Time of assessment (00:00-23:59)

| Audit                                                                                                                                                                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                          | System                | 21 Aug 2020 02:54:26 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Vitals collected 30 mins post dose per protocol' (Site from System). | Kelly Woodell (b) (4) | 21 Aug 2020 00:28:01 |
| User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).                                                     | System                | 21 Aug 2020 00:27:31 |
| User entered '14:31'                                                                                                                                                                                         | Kelly Woodell (b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 14:31' | System | 21 Aug 2020 00:27:31 |



US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

Temperature (xxx.x)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered '97.8' F | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[If Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Pulse \(xxx\)](#)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '75' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate \(xxx\)](#)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '16' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

Systolic Blood Pressure (xxx)

| Audit              | User                             | Time (GMT)           |
|--------------------|----------------------------------|----------------------|
| User entered '116' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |



US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

Diastolic Blood Pressure (xxx)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '70' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 00:27:31 |

US3822043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:35

[Was the physical examination performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:28:17 |

US3822043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:35

Date of examination (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '07 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:28:17 |

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[Was study treatment given?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:14:44 |

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[If No, reason not given](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:14:44 |

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:14:44 |



US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '07 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:14:44 |

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '13:59' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:55:35**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 13:59' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[Which arm was used to give treatment?](#)

| Audit                              | User                             | Time (GMT)           |
|------------------------------------|----------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Kelly Woodell (b) (4)<br>(b) (4) | 07 Aug 2020 18:14:44 |

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

[Was the sample collected?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:28:57 |



US3822043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

Collection date (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '07 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:28:57 |

US3822043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

Collection time (00:00-23:59)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '13:20' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:28:57 |

US3822043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 13:20' | System | 21 Aug 2020 00:28:57 |

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:35

Collection date (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '07 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:29:11 |

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:35

[Lab Test](#)

| Audit                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------|-----------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Kelly Woodell (b) (4) | 21 Aug 2020 00:29:11 |

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:35

[Was the sample collected?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:29:11 |

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:35

Collection time (00:00 - 23:59)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '13:55' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:29:11 |

**US3822043**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 13:55' | System | 21 Aug 2020 00:29:11 |



US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:35

[Lab Test](#)

| Audit                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------|-----------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Kelly Woodell (b) (4) | 21 Aug 2020 00:29:11 |

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:35

[Was the sample collected?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:29:11 |

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:35

Collection time (00:00 - 23:59)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:29:11 |

**US3822043**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 00:29:11 |

US3822043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:29:15 |

**US3822043**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:55:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 00:29:15 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:11:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '00b2b152-94b6-44c7-82c4-41b498af17d7' | System | 07 Aug 2020 19:12:28 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 07 Aug 2020 19:12:28 |



US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '00b2b152-94b6-44c7-82c4-41b498af17d7' | System | 07 Aug 2020 19:12:28 |
| User entered '97.8'                                                                                                                                                                                                                                            | System | 07 Aug 2020 19:12:28 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:17', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '00b2b152-94b6-44c7-82c4-41b498af17d7' | System | 07 Aug 2020 19:12:28 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Aug 2020 19:12:28 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '00b2b152-94b6-44c7-82c4-41b498af17d7' | System | 07 Aug 2020 19:12:28 |
| User entered '07 Aug 2020 15:12'                                                                                                                                                                                                                               | System | 07 Aug 2020 19:12:28 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 14:19' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 16:49' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:18:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '81f7e4e7-93e8-4659-b688-5a9dae15ab91' | System | 08 Aug 2020 00:19:18 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 08 Aug 2020 00:19:18 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:18:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '81f7e4e7-93e8-4659-b688-5a9dae15ab91' | System | 08 Aug 2020 00:19:18 |
| User entered '97.8'                                                                                                                                                                                                                                            | System | 08 Aug 2020 00:19:18 |



US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:18:59', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '81f7e4e7-93e8-4659-b688-5a9dae15ab91' | System | 08 Aug 2020 00:19:18 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Aug 2020 00:19:18 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:19:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '81f7e4e7-93e8-4659-b688-5a9dae15ab91' | System | 08 Aug 2020 00:19:18 |
| User entered '07 Aug 2020 20:19'                                                                                                                                                                                                                               | System | 08 Aug 2020 00:19:18 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 17:44' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 2' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:38:26', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588' | System | 08 Aug 2020 23:40:31 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 08 Aug 2020 23:40:31 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:39:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588' | System | 08 Aug 2020 23:40:31 |
| User entered '98.6'                                                                                                                                                                                                                                            | System | 08 Aug 2020 23:40:31 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588' | System | 08 Aug 2020 23:40:31 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 08 Aug 2020 23:40:31 |



US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| 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).<br>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 'Per day 8 Phone call no medication was taken' (Site from System). | (b) (4), (b) (6)      | 27 Aug 2020 17:40:10 |
| 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).<br>External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:16', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588'<br>User entered '1'                              | Kelly Woodell (b) (4) | 26 Aug 2020 02:07:17 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | System                | 08 Aug 2020 23:40:31 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | System                | 08 Aug 2020 23:40:31 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | System                | 08 Aug 2020 23:40:31 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

To **PREVENT** pain or fever from occurring

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:16', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588' | System | 08 Aug 2020 23:40:31 |
| User entered '0'                                                                                                                                                                                                                                               | System | 08 Aug 2020 23:40:31 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588' | System | 08 Aug 2020 23:40:31 |
| User entered '08 Aug 2020 19:40'                                                                                                                                                                                                                               | System | 08 Aug 2020 23:40:31 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 3' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'dde7c304-9529-4246-bf9d-f876a1d9ece9' | System | 09 Aug 2020 23:26:25 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 09 Aug 2020 23:26:25 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'dde7c304-9529-4246-bf9d-f876a1d9ece9' | System | 09 Aug 2020 23:26:25 |
| User entered '98.5'                                                                                                                                                                                                                                            | System | 09 Aug 2020 23:26:25 |



US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'dde7c304-9529-4246-bf9d-f876a1d9ece9' | System | 09 Aug 2020 23:26:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 09 Aug 2020 23:26:25 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:20', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'dde7c304-9529-4246-bf9d-f876a1d9ece9' | System | 09 Aug 2020 23:26:25 |
| User entered '09 Aug 2020 19:26'                                                                                                                                                                                                                               | System | 09 Aug 2020 23:26:25 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 4' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e129f8bf-c0ae-4748-9798-6bdf93477a92' | System | 10 Aug 2020 23:38:31 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 10 Aug 2020 23:38:31 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e129f8bf-c0ae-4748-9798-6bdf93477a92' | System | 10 Aug 2020 23:38:31 |
| User entered '98.3'                                                                                                                                                                                                                                            | System | 10 Aug 2020 23:38:31 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e129f8bf-c0ae-4748-9798-6bdf93477a92' | System | 10 Aug 2020 23:38:31 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 10 Aug 2020 23:38:31 |



**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:26', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e129f8bf-c0ae-4748-9798-6bdf93477a92' | System | 10 Aug 2020 23:38:31 |
| User entered '10 Aug 2020 19:38'                                                                                                                                                                                                                               | System | 10 Aug 2020 23:38:31 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 5' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:09:47', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '295389d1-605e-4649-a82f-a5db5f406323' | System | 11 Aug 2020 23:10:17 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 11 Aug 2020 23:10:17 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:09:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '295389d1-605e-4649-a82f-a5db5f406323' | System | 11 Aug 2020 23:10:17 |
| User entered '98.5'                                                                                                                                                                                                                                            | System | 11 Aug 2020 23:10:17 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:09:56', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '295389d1-605e-4649-a82f-a5db5f406323' | System | 11 Aug 2020 23:10:17 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Aug 2020 23:10:17 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:09:59', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '295389d1-605e-4649-a82f-a5db5f406323' User entered '11 Aug 2020 19:09' | System | 11 Aug 2020 23:10:17 |
|                                                                                                                                                                                                                                                                                                 | System | 11 Aug 2020 23:10:17 |



US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 6' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:04', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '78069720-283a-429e-879b-e89020aaeb29' | System | 12 Aug 2020 23:59:24 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 12 Aug 2020 23:59:24 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:10', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '78069720-283a-429e-879b-e89020aaeb29' | System | 12 Aug 2020 23:59:24 |
| User entered '98.6'                                                                                                                                                                                                                                            | System | 12 Aug 2020 23:59:24 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:16', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '78069720-283a-429e-879b-e89020aaeb29' | System | 12 Aug 2020 23:59:24 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 12 Aug 2020 23:59:24 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:19', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '78069720-283a-429e-879b-e89020aaeb29' | System | 12 Aug 2020 23:59:24 |
| User entered '12 Aug 2020 19:59'                                                                                                                                                                                                                               | System | 12 Aug 2020 23:59:24 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |



US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 7' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:11:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '8d7e26e9-2eee-4e3a-83ae-619b11035e80' | System | 13 Aug 2020 23:11:59 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 13 Aug 2020 23:11:59 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:11:44', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '8d7e26e9-2eee-4e3a-83ae-619b11035e80' | System | 13 Aug 2020 23:11:59 |
| User entered '98.4'                                                                                                                                                                                                                                            | System | 13 Aug 2020 23:11:59 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:11:48', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '8d7e26e9-2eee-4e3a-83ae-619b11035e80' | System | 13 Aug 2020 23:11:59 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 13 Aug 2020 23:11:59 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:11:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '8d7e26e9-2eee-4e3a-83ae-619b11035e80' | System | 13 Aug 2020 23:11:59 |
| User entered '13 Aug 2020 19:11'                                                                                                                                                                                                                               | System | 13 Aug 2020 23:11:59 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |



**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0185d42b-aca3-4655-ac38-5bcf89636952' | System | 07 Aug 2020 19:13:16 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 07 Aug 2020 19:13:16 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:55', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0185d42b-aca3-4655-ac38-5bcf89636952' | System | 07 Aug 2020 19:13:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Aug 2020 19:13:16 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0185d42b-aca3-4655-ac38-5bcf89636952' | System | 07 Aug 2020 19:13:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Aug 2020 19:13:16 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0185d42b-aca3-4655-ac38-5bcf89636952' | System | 07 Aug 2020 19:13:16 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 07 Aug 2020 19:13:16 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0185d42b-aca3-4655-ac38-5bcf89636952' | System | 07 Aug 2020 19:13:16 |
| User entered '07 Aug 2020 15:13'                                                                                                                                                                                                                               | System | 07 Aug 2020 19:13:16 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 14:19' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 16:49' | System | 07 Aug 2020 18:14:44 |



**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:19:38', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'cbe75e25-2961-44f6-b4f5-540c9949093f' | System | 08 Aug 2020 00:20:21 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 08 Aug 2020 00:20:21 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:19:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'cbe75e25-2961-44f6-b4f5-540c9949093f' | System | 08 Aug 2020 00:20:21 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Aug 2020 00:20:21 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:19:50', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'cbe75e25-2961-44f6-b4f5-540c9949093f' | System | 08 Aug 2020 00:20:21 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Aug 2020 00:20:21 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:02', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'cbe75e25-2961-44f6-b4f5-540c9949093f' User entered 'None (1)' | System | 08 Aug 2020 00:20:21 |
|                                                                                                                                                                                                                                                                                        | System | 08 Aug 2020 00:20:21 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:19', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'cbe75e25-2961-44f6-b4f5-540c9949093f' | System | 08 Aug 2020 00:20:21 |
| User entered '07 Aug 2020 20:20'                                                                                                                                                                                                                               | System | 08 Aug 2020 00:20:21 |

US3822043

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 17:44' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |



US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 2' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:37', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '810d5382-5e53-4e02-b66d-919c76a72eb1' | System | 08 Aug 2020 23:41:13 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 08 Aug 2020 23:41:13 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:41', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '810d5382-5e53-4e02-b66d-919c76a72eb1' | System | 08 Aug 2020 23:41:13 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Aug 2020 23:41:13 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:51', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '810d5382-5e53-4e02-b66d-919c76a72eb1' | System | 08 Aug 2020 23:41:13 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Aug 2020 23:41:13 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '810d5382-5e53-4e02-b66d-919c76a72eb1' | System | 08 Aug 2020 23:41:13 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 08 Aug 2020 23:41:13 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '810d5382-5e53-4e02-b66d-919c76a72eb1' | System | 08 Aug 2020 23:41:13 |
| User entered '08 Aug 2020 19:41'                                                                                                                                                                                                                               | System | 08 Aug 2020 23:41:13 |

US3822043

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |



US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 3' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:35', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3764a53c-68a5-4981-9f87-a812a813ac28' | System | 09 Aug 2020 23:26:54 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 09 Aug 2020 23:26:54 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:38', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3764a53c-68a5-4981-9f87-a812a813ac28' | System | 09 Aug 2020 23:26:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 09 Aug 2020 23:26:54 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3764a53c-68a5-4981-9f87-a812a813ac28' | System | 09 Aug 2020 23:26:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 09 Aug 2020 23:26:54 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:47', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3764a53c-68a5-4981-9f87-a812a813ac28' | System | 09 Aug 2020 23:26:54 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 09 Aug 2020 23:26:54 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:50', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3764a53c-68a5-4981-9f87-a812a813ac28' | System | 09 Aug 2020 23:26:54 |
| User entered '09 Aug 2020 19:26'                                                                                                                                                                                                                               | System | 09 Aug 2020 23:26:54 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |



US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 4' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:31', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '15ba1843-cdab-4323-8f1c-be6660c1900a' | System | 10 Aug 2020 23:39:04 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 10 Aug 2020 23:39:04 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:35', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '15ba1843-cdab-4323-8f1c-be6660c1900a' | System | 10 Aug 2020 23:39:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 10 Aug 2020 23:39:04 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '15ba1843-cdab-4323-8f1c-be6660c1900a' | System | 10 Aug 2020 23:39:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 10 Aug 2020 23:39:04 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '15ba1843-cdab-4323-8f1c-be6660c1900a' | System | 10 Aug 2020 23:39:04 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 10 Aug 2020 23:39:04 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:01', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '15ba1843-cdab-4323-8f1c-be6660c1900a' | System | 10 Aug 2020 23:39:04 |
| User entered '10 Aug 2020 19:39'                                                                                                                                                                                                                               | System | 10 Aug 2020 23:39:04 |

US3822043

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |



US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 5' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2ca7043-e104-4c2f-b573-011ffb622554' | System | 11 Aug 2020 23:10:23 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Aug 2020 23:10:23 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2ca7043-e104-4c2f-b573-011ffb622554' | System | 11 Aug 2020 23:10:23 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Aug 2020 23:10:23 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:12', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2ca7043-e104-4c2f-b573-011ffb622554' | System | 11 Aug 2020 23:10:23 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Aug 2020 23:10:23 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2ca7043-e104-4c2f-b573-011ffb622554' | System | 11 Aug 2020 23:10:23 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 11 Aug 2020 23:10:23 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2ca7043-e104-4c2f-b573-011ffb622554' | System | 11 Aug 2020 23:10:23 |
| User entered '11 Aug 2020 19:10'                                                                                                                                                                                                                               | System | 11 Aug 2020 23:10:23 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |



**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 6' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'be3e61e3-c489-4a00-bb00-91e0b9a9b7a5' | System | 12 Aug 2020 23:59:47 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 12 Aug 2020 23:59:47 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:26', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'be3e61e3-c489-4a00-bb00-91e0b9a9b7a5' | System | 12 Aug 2020 23:59:47 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 12 Aug 2020 23:59:47 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:32', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'be3e61e3-c489-4a00-bb00-91e0b9a9b7a5' | System | 12 Aug 2020 23:59:47 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 12 Aug 2020 23:59:47 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:38', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'be3e61e3-c489-4a00-bb00-91e0b9a9b7a5' | System | 12 Aug 2020 23:59:47 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 12 Aug 2020 23:59:47 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:43', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'be3e61e3-c489-4a00-bb00-91e0b9a9b7a5' | System | 12 Aug 2020 23:59:47 |
| User entered '12 Aug 2020 19:59'                                                                                                                                                                                                                               | System | 12 Aug 2020 23:59:47 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |



US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 7' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:11:56', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '52fed148-e57b-464e-90b2-4c937f077331' | System | 13 Aug 2020 23:12:19 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 13 Aug 2020 23:12:19 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '52fed148-e57b-464e-90b2-4c937f077331' | System | 13 Aug 2020 23:12:19 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 13 Aug 2020 23:12:19 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:03', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '52fed148-e57b-464e-90b2-4c937f077331' | System | 13 Aug 2020 23:12:19 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 13 Aug 2020 23:12:19 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '52fed148-e57b-464e-90b2-4c937f077331' | System | 13 Aug 2020 23:12:19 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 13 Aug 2020 23:12:19 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:11', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '52fed148-e57b-464e-90b2-4c937f077331' | System | 13 Aug 2020 23:12:19 |
| User entered '13 Aug 2020 19:12'                                                                                                                                                                                                                               | System | 13 Aug 2020 23:12:19 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |



US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:23', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' | System | 07 Aug 2020 19:13:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Aug 2020 19:13:52 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:30', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' | System | 07 Aug 2020 19:13:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Aug 2020 19:13:52 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' | System | 07 Aug 2020 19:13:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Aug 2020 19:13:52 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' | System | 07 Aug 2020 19:13:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Aug 2020 19:13:52 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' | System | 07 Aug 2020 19:13:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Aug 2020 19:13:52 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:41', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' | System | 07 Aug 2020 19:13:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Aug 2020 19:13:52 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:46', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' | System | 07 Aug 2020 19:13:52 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Aug 2020 19:13:52 |



**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:49', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' | System | 07 Aug 2020 19:13:52 |
| User entered '07 Aug 2020 15:13'                                                                                                                                                                                                                               | System | 07 Aug 2020 19:13:52 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 14:19' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 16:49' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' | System | 08 Aug 2020 00:21:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Aug 2020 00:21:18 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:21:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' | System | 08 Aug 2020 00:21:18 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 08 Aug 2020 00:21:18 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' | System | 08 Aug 2020 00:21:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Aug 2020 00:21:18 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' | System | 08 Aug 2020 00:21:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Aug 2020 00:21:18 |



**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' | System | 08 Aug 2020 00:21:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Aug 2020 00:21:18 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:45', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' | System | 08 Aug 2020 00:21:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Aug 2020 00:21:18 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:56', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' | System | 08 Aug 2020 00:21:18 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Aug 2020 00:21:18 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:21:17', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' | System | 08 Aug 2020 00:21:18 |
| User entered '07 Aug 2020 20:21'                                                                                                                                                                                                                               | System | 08 Aug 2020 00:21:18 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Aug 2020 17:44' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 2' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' | System | 08 Aug 2020 23:41:48 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Aug 2020 23:41:48 |



**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' | System | 08 Aug 2020 23:41:48 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 08 Aug 2020 23:41:48 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' | System | 08 Aug 2020 23:41:48 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Aug 2020 23:41:48 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' | System | 08 Aug 2020 23:41:48 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Aug 2020 23:41:48 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:30', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' | System | 08 Aug 2020 23:41:48 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Aug 2020 23:41:48 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' | System | 08 Aug 2020 23:41:48 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Aug 2020 23:41:48 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:37', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' | System | 08 Aug 2020 23:41:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Aug 2020 23:41:48 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:44', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' | System | 08 Aug 2020 23:41:48 |
| User entered '08 Aug 2020 19:41'                                                                                                                                                                                                                               | System | 08 Aug 2020 23:41:48 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |



US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 3' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' | System | 09 Aug 2020 23:27:21 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 09 Aug 2020 23:27:21 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:01', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered 'None (0)' | System | 09 Aug 2020 23:27:21 |
|                                                                                                                                                                                                                                                                                        | System | 09 Aug 2020 23:27:21 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered 'None (0)' | System | 09 Aug 2020 23:27:21 |
|                                                                                                                                                                                                                                                                                        | System | 09 Aug 2020 23:27:21 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:07', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered 'None (0)' | System | 09 Aug 2020 23:27:21 |
|                                                                                                                                                                                                                                                                                        | System | 09 Aug 2020 23:27:21 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:09', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' | System | 09 Aug 2020 23:27:21 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 09 Aug 2020 23:27:21 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:12', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered 'None (0)' | System | 09 Aug 2020 23:27:21 |
|                                                                                                                                                                                                                                                                                        | System | 09 Aug 2020 23:27:21 |



US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' | System | 09 Aug 2020 23:27:21 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 09 Aug 2020 23:27:21 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' | System | 09 Aug 2020 23:27:21 |
| User entered '09 Aug 2020 19:27'                                                                                                                                                                                                                               | System | 09 Aug 2020 23:27:21 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 4' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' | System | 10 Aug 2020 23:39:30 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 10 Aug 2020 23:39:30 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:07', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' | System | 10 Aug 2020 23:39:30 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 10 Aug 2020 23:39:30 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:11', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' | System | 10 Aug 2020 23:39:30 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 10 Aug 2020 23:39:30 |



US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' | System | 10 Aug 2020 23:39:30 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 10 Aug 2020 23:39:30 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' | System | 10 Aug 2020 23:39:30 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 10 Aug 2020 23:39:30 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' | System | 10 Aug 2020 23:39:30 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 10 Aug 2020 23:39:30 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' | System | 10 Aug 2020 23:39:30 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 10 Aug 2020 23:39:30 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' User entered '10 Aug 2020 19:39' | System | 10 Aug 2020 23:39:30 |
|                                                                                                                                                                                                                                                                                                 | System | 10 Aug 2020 23:39:30 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 5' | System | 07 Aug 2020 18:14:44 |



**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' | System | 11 Aug 2020 23:10:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Aug 2020 23:10:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' | System | 11 Aug 2020 23:10:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Aug 2020 23:10:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' | System | 11 Aug 2020 23:10:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Aug 2020 23:10:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' | System | 11 Aug 2020 23:10:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Aug 2020 23:10:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:31', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' | System | 11 Aug 2020 23:10:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Aug 2020 23:10:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' | System | 11 Aug 2020 23:10:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 11 Aug 2020 23:10:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' | System | 11 Aug 2020 23:10:44 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Aug 2020 23:10:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' | System | 11 Aug 2020 23:10:44 |
| User entered '11 Aug 2020 19:10'                                                                                                                                                                                                                               | System | 11 Aug 2020 23:10:44 |



US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 6' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:51', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' | System | 13 Aug 2020 00:00:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 13 Aug 2020 00:00:12 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:54', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' | System | 13 Aug 2020 00:00:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 13 Aug 2020 00:00:12 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:56', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' | System | 13 Aug 2020 00:00:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 13 Aug 2020 00:00:12 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' | System | 13 Aug 2020 00:00:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 13 Aug 2020 00:00:12 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T20:00:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' | System | 13 Aug 2020 00:00:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 13 Aug 2020 00:00:12 |



**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T20:00:02', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' | System | 13 Aug 2020 00:00:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 13 Aug 2020 00:00:12 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T20:00:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' | System | 13 Aug 2020 00:00:12 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 13 Aug 2020 00:00:12 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T20:00:09', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' | System | 13 Aug 2020 00:00:12 |
| User entered '12 Aug 2020 20:00'                                                                                                                                                                                                                               | System | 13 Aug 2020 00:00:12 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 7' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:17', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered 'None (0)' | System | 13 Aug 2020 23:12:38 |
|                                                                                                                                                                                                                                                                                        | System | 13 Aug 2020 23:12:38 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:19', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered 'None (0)' | System | 13 Aug 2020 23:12:38 |
|                                                                                                                                                                                                                                                                                        | System | 13 Aug 2020 23:12:38 |



US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered 'None (0)' | System | 13 Aug 2020 23:12:38 |
|                                                                                                                                                                                                                                                                                        | System | 13 Aug 2020 23:12:38 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:23', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered 'None (0)' | System | 13 Aug 2020 23:12:38 |
|                                                                                                                                                                                                                                                                                        | System | 13 Aug 2020 23:12:38 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' | System | 13 Aug 2020 23:12:38 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 13 Aug 2020 23:12:38 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' | System | 13 Aug 2020 23:12:38 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 13 Aug 2020 23:12:38 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:31', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' | System | 13 Aug 2020 23:12:38 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 13 Aug 2020 23:12:38 |

**US3822043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:34', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' | System | 13 Aug 2020 23:12:38 |
| User entered '13 Aug 2020 19:12'                                                                                                                                                                                                                               | System | 13 Aug 2020 23:12:38 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 18:14:44 |



US3822043

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:30:37 |

US3822043

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '17 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:30:37 |

US3822043

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--------------------------------------------|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:30:37 |

US3822043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:30:37 |

US3822043

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:55:35**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 21 Aug 2020 00:30:40 |

**US3822043**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:55:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 00:30:40 |

US3822043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 00:14:31 |

US3822043

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '24 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 00:14:31 |



US3822043

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--------------------------------------------|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 00:14:31 |

US3822043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 00:14:31 |

US3822043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 00:14:34 |

**US3822043**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:55:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Sep 2020 00:14:34 |

US3822043

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 00:14:44 |

US3822043

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '31 Aug 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 00:14:44 |

US3822043

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--------------------------------------------|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 00:14:44 |

US3822043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 00:14:44 |



US3822043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 00:14:47 |

US3822043

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:55:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Sep 2020 00:14:47 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

[Was this visit performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 18:34:25 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

Visit date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                    | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).                                                                                                             | (b) (4), (b) (6)      | 03 Sep 2020 11:09:07 |
| Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Date is correct as is. Per protocol there is a -3/+7 day window and the visit falls within that window.' (Site from System). | Kelly Woodell (b) (4) | 02 Sep 2020 18:34:46 |
| User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).                                                                                                             | System                | 02 Sep 2020 18:34:32 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System).                                                                                                                                                                  | System                | 02 Sep 2020 18:34:32 |
| User entered '02 Sep 2020' reason for change: Data Entry Error                                                                                                                                                                                           | Kelly Woodell (b) (4) | 02 Sep 2020 18:34:32 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).                                                                                                                                                                  | System                | 02 Sep 2020 18:34:25 |
| User entered '02 Sep 202' (non-conformant).                                                                                                                                                                                                              | Kelly Woodell (b) (4) | 02 Sep 2020 18:34:25 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 18:34:25 |

**US3822043**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:55:35**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 02 Sep 2020 18:34:25 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Timepoint](#)

| Audit                                            | User                            | Time (GMT)           |
|--------------------------------------------------|---------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Were vital signs assessed?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:16:17 |



US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User entered '2 Sep 2020' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

Time of assessment (00:00-23:59)

| Audit                | User                            | Time (GMT)           |
|----------------------|---------------------------------|----------------------|
| User entered '13:43' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '2 Sep 2020 13:43' | System | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

Temperature (xxx.x)

| Audit                 | User                            | Time (GMT)           |
|-----------------------|---------------------------------|----------------------|
| User entered '98.5' F | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Route of measurement](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (Oral)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[If Other, specify](#)

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

Pulse (xxx)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '86' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 06 Oct 2020 20:16:17 |



US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate \(xxx\)](#)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '18' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

Systolic Blood Pressure (xxx)

| Audit              | User                            | Time (GMT)           |
|--------------------|---------------------------------|----------------------|
| User entered '130' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

Diastolic Blood Pressure (xxx)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '84' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:35

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 06 Oct 2020 20:16:17 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Timepoint](#)

| Audit                                              | User                            | Time (GMT)           |
|----------------------------------------------------|---------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Were vital signs assessed?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:17:37 |



US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User entered '2 Sep 2020' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

Time of assessment (00:00-23:59)

| Audit                | User                            | Time (GMT)           |
|----------------------|---------------------------------|----------------------|
| User entered '15:10' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '2 Sep 2020 15:10' | System | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

Temperature (xxx.x)

| Audit                 | User                            | Time (GMT)           |
|-----------------------|---------------------------------|----------------------|
| User entered '99.1' F | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Route of measurement](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (Oral)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[If Other, specify](#)

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

Pulse (xxx)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '81' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 06 Oct 2020 20:17:37 |



US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate \(xxx\)](#)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '18' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

Systolic Blood Pressure (xxx)

| Audit              | User                            | Time (GMT)           |
|--------------------|---------------------------------|----------------------|
| User entered '125' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

Diastolic Blood Pressure (xxx)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '76' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:35

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 06 Oct 2020 20:17:37 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:35

[Was the physical examination performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 18:35:01 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:35

Date of examination (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '02 Sep 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 18:35:01 |



US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[Was study treatment given?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 18:35:19 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[If No, reason not given](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 18:35:19 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 18:35:19 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '02 Sep 2020' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 18:35:19 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '14:31' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 18:35:19 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 14:31' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[Which arm was used to give treatment?](#)

| Audit                              | User                             | Time (GMT)           |
|------------------------------------|----------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 18:35:19 |



US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:35

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

[Was the sample collected?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:18:21 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

Collection date (dd MMM yyyy)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User entered '2 Sep 2020' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:18:21 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

Collection time (00:00-23:59)

| Audit                | User                            | Time (GMT)           |
|----------------------|---------------------------------|----------------------|
| User entered '14:05' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:18:21 |

**US3822043**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:55:35**

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '2 Sep 2020 14:05' | System | 06 Oct 2020 20:18:21 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:35

Collection date (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User entered '2 Sep 2020' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:18:38 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:35

[Lab Test](#)

| Audit                                                        | User                            | Time (GMT)           |
|--------------------------------------------------------------|---------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:18:38 |



US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:35

[Was the sample collected?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:18:38 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:35

Collection time (00:00 - 23:59)

| Audit                | User                            | Time (GMT)           |
|----------------------|---------------------------------|----------------------|
| User entered '14:14' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:18:38 |

**US3822043**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '2 Sep 2020 14:14' | System | 06 Oct 2020 20:18:38 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:35

[Lab Test](#)

| Audit                                                        | User                            | Time (GMT)           |
|--------------------------------------------------------------|---------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:18:38 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:35

[Was the sample collected?](#)

| Audit                 | User                            | Time (GMT)           |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:18:38 |

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:35

Collection time (00:00 - 23:59)

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:18:38 |

**US3822043**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 20:18:38 |

US3822043

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:55:35**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kelly Woodell (b) (4)<br>(b) (4) | 02 Sep 2020 18:35:29 |



US3822043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Sep 2020 18:35:29 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'eea885fd-0bed-4322-9d91-51f7b74f56ea' User entered 'Yes (Y)' | System | 02 Sep 2020 20:00:26 |
|                                                                                                                                                                                                                                                                                       | System | 02 Sep 2020 20:00:26 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'eea885fd-0bed-4322-9d91-51f7b74f56ea' User entered '97.4' | System | 02 Sep 2020 20:00:26 |
|                                                                                                                                                                                                                                                                                    | System | 02 Sep 2020 20:00:26 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:12', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'eea885fd-0bed-4322-9d91-51f7b74f56ea' | System | 02 Sep 2020 20:00:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 20:00:26 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'eea885fd-0bed-4322-9d91-51f7b74f56ea' | System | 02 Sep 2020 20:00:26 |
| User entered '02 Sep 2020 16:00'                                                                                                                                                                                                                               | System | 02 Sep 2020 20:00:26 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 14:51' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 17:21' | System | 02 Sep 2020 18:35:19 |



US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:53:50', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '175d3d55-401f-42a4-a80b-08dc86b1f40a' | System | 03 Sep 2020 00:54:15 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 03 Sep 2020 00:54:15 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '175d3d55-401f-42a4-a80b-08dc86b1f40a' User entered '97.9' | System | 03 Sep 2020 00:54:15 |
|                                                                                                                                                                                                                                                                                    | System | 03 Sep 2020 00:54:15 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '175d3d55-401f-42a4-a80b-08dc86b1f40a' | System | 03 Sep 2020 00:54:15 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 00:54:15 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:11', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '175d3d55-401f-42a4-a80b-08dc86b1f40a' | System | 03 Sep 2020 00:54:15 |
| User entered '02 Sep 2020 20:54'                                                                                                                                                                                                                               | System | 03 Sep 2020 00:54:15 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 18:16' | System | 02 Sep 2020 18:35:19 |

US3822043

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 2' | System | 02 Sep 2020 18:35:19 |



US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:35:40', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'ad8c12e6-4987-42d6-90bd-2cf4182be6d2' | System | 03 Sep 2020 23:36:08 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 03 Sep 2020 23:36:08 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:35:51', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'ad8c12e6-4987-42d6-90bd-2cf4182be6d2' | System | 03 Sep 2020 23:36:08 |
| User entered '100.9'                                                                                                                                                                                                                                           | System | 03 Sep 2020 23:36:08 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:35:55', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'ad8c12e6-4987-42d6-90bd-2cf4182be6d2' | System | 03 Sep 2020 23:36:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 23:36:08 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:36:02', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'ad8c12e6-4987-42d6-90bd-2cf4182be6d2' | System | 03 Sep 2020 23:36:08 |
| User entered '03 Sep 2020 19:36'                                                                                                                                                                                                                               | System | 03 Sep 2020 23:36:08 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 3' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:40:24', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '1e7e0dfd-ca0e-40e4-bf10-857b7dede757' | System | 04 Sep 2020 23:41:26 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 04 Sep 2020 23:41:26 |



US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:09', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '1e7e0dfd-ca0e-40e4-bf10-857b7dede757' | System | 04 Sep 2020 23:41:26 |
| User entered '98.4'                                                                                                                                                                                                                                            | System | 04 Sep 2020 23:41:26 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '1e7e0dfd-ca0e-40e4-bf10-857b7dede757' | System | 04 Sep 2020 23:41:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Sep 2020 23:41:26 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '1e7e0dfd-ca0e-40e4-bf10-857b7dede757' | System | 04 Sep 2020 23:41:26 |
| User entered '04 Sep 2020 19:41'                                                                                                                                                                                                                               | System | 04 Sep 2020 23:41:26 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |

US3822043

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 4' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:20', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54d1b79b-2319-402d-9b5f-4440d7e2596b' | System | 06 Sep 2020 00:15:40 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 06 Sep 2020 00:15:40 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54d1b79b-2319-402d-9b5f-4440d7e2596b' | System | 06 Sep 2020 00:15:40 |
| User entered '97.0'                                                                                                                                                                                                                                            | System | 06 Sep 2020 00:15:40 |



US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:30', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54d1b79b-2319-402d-9b5f-4440d7e2596b' | System | 06 Sep 2020 00:15:40 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 00:15:40 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54d1b79b-2319-402d-9b5f-4440d7e2596b' | System | 06 Sep 2020 00:15:40 |
| User entered '05 Sep 2020 20:15'                                                                                                                                                                                                                               | System | 06 Sep 2020 00:15:40 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 5' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:16:17', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '355524b2-05c1-4179-9ff5-a11fa41439e0' | System | 07 Sep 2020 00:16:41 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 07 Sep 2020 00:16:41 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:16:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '355524b2-05c1-4179-9ff5-a11fa41439e0' | System | 07 Sep 2020 00:16:41 |
| User entered '97.5'                                                                                                                                                                                                                                            | System | 07 Sep 2020 00:16:41 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:16:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '355524b2-05c1-4179-9ff5-a11fa41439e0' | System | 07 Sep 2020 00:16:41 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 00:16:41 |



**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:16:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '355524b2-05c1-4179-9ff5-a11fa41439e0' | System | 07 Sep 2020 00:16:41 |
| User entered '06 Sep 2020 20:16'                                                                                                                                                                                                                               | System | 07 Sep 2020 00:16:41 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |

US3822043

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 6' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:02:48', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f47d9670-e4c2-4077-9292-e1bc4a5aa632' | System | 08 Sep 2020 00:03:08 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 08 Sep 2020 00:03:08 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:02:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f47d9670-e4c2-4077-9292-e1bc4a5aa632' | System | 08 Sep 2020 00:03:08 |
| User entered '98.1'                                                                                                                                                                                                                                            | System | 08 Sep 2020 00:03:08 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:01', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f47d9670-e4c2-4077-9292-e1bc4a5aa632' | System | 08 Sep 2020 00:03:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Sep 2020 00:03:08 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:04', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f47d9670-e4c2-4077-9292-e1bc4a5aa632' | System | 08 Sep 2020 00:03:08 |
| User entered '07 Sep 2020 20:03'                                                                                                                                                                                                                               | System | 08 Sep 2020 00:03:08 |



US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 7' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:34:51', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '217d420b-1d1a-4679-854a-d5ac8fc2ef0c' | System | 08 Sep 2020 23:35:15 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 08 Sep 2020 23:35:15 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:34:59', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '217d420b-1d1a-4679-854a-d5ac8fc2ef0c' User entered '97.5' | System | 08 Sep 2020 23:35:15 |
|                                                                                                                                                                                                                                                                                    | System | 08 Sep 2020 23:35:15 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '217d420b-1d1a-4679-854a-d5ac8fc2ef0c' | System | 08 Sep 2020 23:35:15 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Sep 2020 23:35:15 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:10', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '217d420b-1d1a-4679-854a-d5ac8fc2ef0c' | System | 08 Sep 2020 23:35:15 |
| User entered '08 Sep 2020 19:35'                                                                                                                                                                                                                               | System | 08 Sep 2020 23:35:15 |

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |



US3822043

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:32', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f4f9c2d5-48e4-4a5f-a402-066e2c8b072e' | System | 02 Sep 2020 20:01:05 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 20:01:05 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f4f9c2d5-48e4-4a5f-a402-066e2c8b072e' | System | 02 Sep 2020 20:01:05 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 20:01:05 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:48', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f4f9c2d5-48e4-4a5f-a402-066e2c8b072e' | System | 02 Sep 2020 20:01:05 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 20:01:05 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f4f9c2d5-48e4-4a5f-a402-066e2c8b072e' | System | 02 Sep 2020 20:01:05 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 20:01:05 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f4f9c2d5-48e4-4a5f-a402-066e2c8b072e' | System | 02 Sep 2020 20:01:05 |
| User entered '02 Sep 2020 16:01'                                                                                                                                                                                                                               | System | 02 Sep 2020 20:01:05 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 14:51' | System | 02 Sep 2020 18:35:19 |



US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 17:21' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e84add4a-2eb0-4fa0-ba0f-2afecf3fc7cd' | System | 03 Sep 2020 00:55:14 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 00:55:14 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:26', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e84add4a-2eb0-4fa0-ba0f-2afecf3fc7cd' | System | 03 Sep 2020 00:55:14 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 00:55:14 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e84add4a-2eb0-4fa0-ba0f-2afecf3fc7cd' | System | 03 Sep 2020 00:55:14 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 00:55:14 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e84add4a-2eb0-4fa0-ba0f-2afecf3fc7cd' | System | 03 Sep 2020 00:55:14 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 00:55:14 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:11', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e84add4a-2eb0-4fa0-ba0f-2afecf3fc7cd' | System | 03 Sep 2020 00:55:14 |
| User entered '02 Sep 2020 20:55'                                                                                                                                                                                                                               | System | 03 Sep 2020 00:55:14 |

US3822043

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 18:16' | System | 02 Sep 2020 18:35:19 |



US3822043

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 2' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:36:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '627ddce7-ee2c-426c-b9ee-af696d28660c' | System | 03 Sep 2020 23:37:34 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 03 Sep 2020 23:37:34 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:02', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '627ddce7-ee2c-426c-b9ee-af696d28660c' | System | 03 Sep 2020 23:37:34 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 23:37:34 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:17', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '627ddce7-ee2c-426c-b9ee-af696d28660c' | System | 03 Sep 2020 23:37:34 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 23:37:34 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:23', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '627ddce7-ee2c-426c-b9ee-af696d28660c' | System | 03 Sep 2020 23:37:34 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 23:37:34 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '627ddce7-ee2c-426c-b9ee-af696d28660c' | System | 03 Sep 2020 23:37:34 |
| User entered '03 Sep 2020 19:37'                                                                                                                                                                                                                               | System | 03 Sep 2020 23:37:34 |

US3822043

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |



US3822043

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 3' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55b958c5-8516-414f-b25b-9c8a318d9fab' | System | 04 Sep 2020 23:42:10 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 04 Sep 2020 23:42:10 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:43', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55b958c5-8516-414f-b25b-9c8a318d9fab' | System | 04 Sep 2020 23:42:10 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Sep 2020 23:42:10 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:54', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55b958c5-8516-414f-b25b-9c8a318d9fab' | System | 04 Sep 2020 23:42:10 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Sep 2020 23:42:10 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55b958c5-8516-414f-b25b-9c8a318d9fab' | System | 04 Sep 2020 23:42:10 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 23:42:10 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55b958c5-8516-414f-b25b-9c8a318d9fab' | System | 04 Sep 2020 23:42:10 |
| User entered '04 Sep 2020 19:42'                                                                                                                                                                                                                               | System | 04 Sep 2020 23:42:10 |

US3822043

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |



US3822043

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 4' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:43', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2489d20b-a2be-4f93-96fa-962761e61e98' | System | 06 Sep 2020 00:16:16 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 06 Sep 2020 00:16:16 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2489d20b-a2be-4f93-96fa-962761e61e98' | System | 06 Sep 2020 00:16:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 00:16:16 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2489d20b-a2be-4f93-96fa-962761e61e98' | System | 06 Sep 2020 00:16:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 00:16:16 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:04', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2489d20b-a2be-4f93-96fa-962761e61e98' | System | 06 Sep 2020 00:16:16 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 00:16:16 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:14', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2489d20b-a2be-4f93-96fa-962761e61e98' | System | 06 Sep 2020 00:16:16 |
| User entered '05 Sep 2020 20:16'                                                                                                                                                                                                                               | System | 06 Sep 2020 00:16:16 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |



US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 5' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:16:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2e9f6a96-5c0b-4c4c-9ab9-0170e48b8a35' | System | 07 Sep 2020 00:17:36 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 00:17:36 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:16', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2e9f6a96-5c0b-4c4c-9ab9-0170e48b8a35' | System | 07 Sep 2020 00:17:36 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 00:17:36 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2e9f6a96-5c0b-4c4c-9ab9-0170e48b8a35' | System | 07 Sep 2020 00:17:36 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 00:17:36 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2e9f6a96-5c0b-4c4c-9ab9-0170e48b8a35' | System | 07 Sep 2020 00:17:36 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 00:17:36 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:30', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2e9f6a96-5c0b-4c4c-9ab9-0170e48b8a35' | System | 07 Sep 2020 00:17:36 |
| User entered '06 Sep 2020 20:17'                                                                                                                                                                                                                               | System | 07 Sep 2020 00:17:36 |

US3822043

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |



US3822043

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 6' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:10', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0df3c28f-7003-4cdf-8153-a464a19ceeeef' | System | 08 Sep 2020 00:03:37 |
| User entered 'None (1)'                                                                                                                                                                                                                                         | System | 08 Sep 2020 00:03:37 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0df3c28f-7003-4cdf-8153-a464a19ceeeef' | System | 08 Sep 2020 00:03:37 |
| User entered 'No (N)'                                                                                                                                                                                                                                           | System | 08 Sep 2020 00:03:37 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0df3c28f-7003-4cdf-8153-a464a19ceeeef' | System | 08 Sep 2020 00:03:37 |
| User entered 'No (N)'                                                                                                                                                                                                                                           | System | 08 Sep 2020 00:03:37 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0df3c28f-7003-4cdf-8153-a464a19ceef' | System | 08 Sep 2020 00:03:37 |
| User entered 'None (1)'                                                                                                                                                                                                                                       | System | 08 Sep 2020 00:03:37 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:28', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0df3c28f-7003-4cdf-8153-a464a19ceeeef' | System | 08 Sep 2020 00:03:37 |
| User entered '07 Sep 2020 20:03'                                                                                                                                                                                                                                | System | 08 Sep 2020 00:03:37 |

US3822043

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |



US3822043

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 7' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '53d05e95-8ecc-4d17-a1cb-0b0ffca16da1' | System | 08 Sep 2020 23:35:36 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 23:35:36 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '53d05e95-8ecc-4d17-a1cb-0b0ffca16da1' | System | 08 Sep 2020 23:35:36 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Sep 2020 23:35:36 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:23', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '53d05e95-8ecc-4d17-a1cb-0b0ffca16da1' | System | 08 Sep 2020 23:35:36 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Sep 2020 23:35:36 |

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:26', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '53d05e95-8ecc-4d17-a1cb-0b0ffca16da1' | System | 08 Sep 2020 23:35:36 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 23:35:36 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '53d05e95-8ecc-4d17-a1cb-0b0ffca16da1' | System | 08 Sep 2020 23:35:36 |
| User entered '08 Sep 2020 19:35'                                                                                                                                                                                                                               | System | 08 Sep 2020 23:35:36 |

US3822043

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |



US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 18:35:19 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' | System | 02 Sep 2020 20:01:36 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 20:01:36 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:09', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' | System | 02 Sep 2020 20:01:36 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 20:01:36 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:12', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' | System | 02 Sep 2020 20:01:36 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 20:01:36 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' | System | 02 Sep 2020 20:01:36 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 20:01:36 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' | System | 02 Sep 2020 20:01:36 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 20:01:36 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:20', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' | System | 02 Sep 2020 20:01:36 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 20:01:36 |



US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:28', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' | System | 02 Sep 2020 20:01:36 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 20:01:36 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' | System | 02 Sep 2020 20:01:36 |
| User entered '02 Sep 2020 16:01'                                                                                                                                                                                                                               | System | 02 Sep 2020 20:01:36 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 14:51' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 17:21' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:16', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' | System | 03 Sep 2020 00:55:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 00:55:52 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' | System | 03 Sep 2020 00:55:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 00:55:52 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:24', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' | System | 03 Sep 2020 00:55:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 00:55:52 |



US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' | System | 03 Sep 2020 00:55:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 00:55:52 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' | System | 03 Sep 2020 00:55:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 00:55:52 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:31', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' | System | 03 Sep 2020 00:55:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 00:55:52 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' | System | 03 Sep 2020 00:55:52 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 00:55:52 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:47', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' | System | 03 Sep 2020 00:55:52 |
| User entered '02 Sep 2020 20:55'                                                                                                                                                                                                                               | System | 03 Sep 2020 00:55:52 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 18:16' | System | 02 Sep 2020 18:35:19 |

US3822043

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 2' | System | 02 Sep 2020 18:35:19 |



**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:37', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94' | System | 03 Sep 2020 23:38:39 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 03 Sep 2020 23:38:39 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:43', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94' | System | 03 Sep 2020 23:38:39 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 03 Sep 2020 23:38:39 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:53', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94' | System | 03 Sep 2020 23:38:39 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 03 Sep 2020 23:38:39 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:38:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94' | System | 03 Sep 2020 23:38:39 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 03 Sep 2020 23:38:39 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:38:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94' | System | 03 Sep 2020 23:38:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 23:38:39 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:38:19', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94' | System | 03 Sep 2020 23:38:39 |
| User entered 'Some interference with activity not requiring medical attention (2)'                                                                                                                                                                             | System | 03 Sep 2020 23:38:39 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:38:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94' | System | 03 Sep 2020 23:38:39 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 23:38:39 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:38:34', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94' | System | 03 Sep 2020 23:38:39 |
| User entered '03 Sep 2020 19:38'                                                                                                                                                                                                                               | System | 03 Sep 2020 23:38:39 |



US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 3' | System | 02 Sep 2020 18:35:19 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' | System | 04 Sep 2020 23:43:14 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 04 Sep 2020 23:43:14 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:31', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' | System | 04 Sep 2020 23:43:14 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 04 Sep 2020 23:43:14 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' | System | 04 Sep 2020 23:43:14 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 04 Sep 2020 23:43:14 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' | System | 04 Sep 2020 23:43:14 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 04 Sep 2020 23:43:14 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:46', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' | System | 04 Sep 2020 23:43:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 23:43:14 |



**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:54', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' | System | 04 Sep 2020 23:43:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 23:43:14 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' | System | 04 Sep 2020 23:43:14 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Sep 2020 23:43:14 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:43:07', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' | System | 04 Sep 2020 23:43:14 |
| User entered '04 Sep 2020 19:43'                                                                                                                                                                                                                               | System | 04 Sep 2020 23:43:14 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 4' | System | 02 Sep 2020 18:35:19 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:19', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' | System | 06 Sep 2020 00:17:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 00:17:04 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' | System | 06 Sep 2020 00:17:04 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 06 Sep 2020 00:17:04 |



US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:32', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' | System | 06 Sep 2020 00:17:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 00:17:04 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:37', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' | System | 06 Sep 2020 00:17:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 00:17:04 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:41', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' | System | 06 Sep 2020 00:17:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 00:17:04 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:44', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' | System | 06 Sep 2020 00:17:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 00:17:04 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:51', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' | System | 06 Sep 2020 00:17:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 00:17:04 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' | System | 06 Sep 2020 00:17:04 |
| User entered '05 Sep 2020 20:16'                                                                                                                                                                                                                               | System | 06 Sep 2020 00:17:04 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |



US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 5' | System | 02 Sep 2020 18:35:19 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:35', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' | System | 07 Sep 2020 00:18:16 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 00:18:16 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:53', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' | System | 07 Sep 2020 00:18:16 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 07 Sep 2020 00:18:16 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:56', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' | System | 07 Sep 2020 00:18:16 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 00:18:16 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:59', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' | System | 07 Sep 2020 00:18:16 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 00:18:16 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:18:01', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' | System | 07 Sep 2020 00:18:16 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 00:18:16 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:18:03', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' | System | 07 Sep 2020 00:18:16 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 00:18:16 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:18:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' | System | 07 Sep 2020 00:18:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 00:18:16 |



**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:18:11', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' | System | 07 Sep 2020 00:18:16 |
| User entered '06 Sep 2020 20:18'                                                                                                                                                                                                                               | System | 07 Sep 2020 00:18:16 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 6' | System | 02 Sep 2020 18:35:19 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:32', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' | System | 08 Sep 2020 00:04:03 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 00:04:03 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:35', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' | System | 08 Sep 2020 00:04:03 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 00:04:03 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' | System | 08 Sep 2020 00:04:03 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 00:04:03 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:41', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' | System | 08 Sep 2020 00:04:03 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 00:04:03 |



**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:43', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' | System | 08 Sep 2020 00:04:03 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 00:04:03 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:45', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' | System | 08 Sep 2020 00:04:03 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 00:04:03 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:49', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' | System | 08 Sep 2020 00:04:03 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Sep 2020 00:04:03 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' | System | 08 Sep 2020 00:04:03 |
| User entered '07 Sep 2020 20:03'                                                                                                                                                                                                                               | System | 08 Sep 2020 00:04:03 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |

US3822043

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 18:35:19 |
| User entered 'Day 7' | System | 02 Sep 2020 18:35:19 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:38', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' | System | 08 Sep 2020 23:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 23:36:11 |



**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:40', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' | System | 08 Sep 2020 23:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 23:36:11 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:44', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' | System | 08 Sep 2020 23:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 23:36:11 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:48', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' | System | 08 Sep 2020 23:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 23:36:11 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:50', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' | System | 08 Sep 2020 23:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 23:36:11 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:53', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' | System | 08 Sep 2020 23:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 23:36:11 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:36:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' | System | 08 Sep 2020 23:36:11 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Sep 2020 23:36:11 |

**US3822043**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:55:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:36:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' | System | 08 Sep 2020 23:36:11 |
| User entered '08 Sep 2020 19:36'                                                                                                                                                                                                                               | System | 08 Sep 2020 23:36:11 |

US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 18:35:19 |



US3822043

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:55:35

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 18:35:19 |

US3822043

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Was Contact Attempted?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:25:46 |

US3822043

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User entered '11 Sep 2020' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:25:46 |

US3822043

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                            | Time (GMT)           |
|--------------------------------------------|---------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:25:46 |

US3822043

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:25:46 |

US3822043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

[Is the participant continuing to the next visit?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:25:54 |

US3822043

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:55:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 20:25:54 |

US3822043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Was Contact Attempted?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:26:32 |



US3822043

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User entered '18 Sep 2020' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:26:32 |

US3822043

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                            | Time (GMT)           |
|--------------------------------------------|---------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:26:32 |

US3822043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:26:32 |

US3822043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

[Is the participant continuing to the next visit?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:26:46 |

US3822043

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:55:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 20:26:46 |

US3822043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Was Contact Attempted?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:27:06 |

US3822043

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User entered '25 Sep 2020' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:27:06 |

US3822043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Please select one status for the follow-up contact](#)

| Audit                                      | User                            | Time (GMT)           |
|--------------------------------------------|---------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:27:06 |



US3822043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:27:06 |

US3822043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

[Is the participant continuing to the next visit?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:27:21 |

US3822043

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:55:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 20:27:21 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

[Was this visit performed?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:27:34 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User entered '1 Oct 2020' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:27:34 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:35

Was visit performed at the participant's home or at the clinic?

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:27:34 |

US3822043

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:55:35**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 06 Oct 2020 20:27:34 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[Were vital signs assessed?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:05 |



US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User entered '1 Oct 2020' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:05 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

Time of assessment (00:00-23:59)

| Audit                | User                            | Time (GMT)           |
|----------------------|---------------------------------|----------------------|
| User entered '13:20' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:05 |

**US3822043**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:55:35**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '1 Oct 2020 13:20' | System | 06 Oct 2020 20:28:05 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

Temperature (xxx.x)

| Audit                 | User                            | Time (GMT)           |
|-----------------------|---------------------------------|----------------------|
| User entered '98.2' F | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:05 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[Route of measurement](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (Oral)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:05 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[If Other, specify](#)

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:05 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

Pulse (xxx)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '88' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:05 |

**US3822043**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:55:35**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 06 Oct 2020 20:28:05 |



US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate \(xxx\)](#)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '20' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:05 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 06 Oct 2020 20:28:05 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

Systolic Blood Pressure (xxx)

| Audit              | User                            | Time (GMT)           |
|--------------------|---------------------------------|----------------------|
| User entered '138' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:05 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 06 Oct 2020 20:28:05 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

Diastolic Blood Pressure (xxx)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '76' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:05 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:35

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 06 Oct 2020 20:28:05 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:35

[Was the physical examination performed?](#)

| Audit                 | User                            | Time (GMT)           |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:15 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:35

Date of examination (*dd MMM yyyy*)

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:15 |



US3822043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

[Was the sample collected?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:35 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

Collection date (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User entered '1 Oct 2020' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:35 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

Collection time (00:00-23:59)

| Audit                | User                            | Time (GMT)           |
|----------------------|---------------------------------|----------------------|
| User entered '13:39' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:35 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:35

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '1 Oct 2020 13:39' | System | 06 Oct 2020 20:28:35 |

US3822043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

[Is the participant continuing to the next visit?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 06 Oct 2020 20:28:41 |

**US3822043**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:55:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 20:28:41 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 64' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-11T14:11:24', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0455e469-17bd-470b-b1f5-5ee48dd6378d' User entered 'Yes (Y)' | System | 11 Oct 2020 18:12:16 |
|                                                                                                                                                                                                                                                                                       | System | 11 Oct 2020 18:12:16 |



US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-11T14:11:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0455e469-17bd-470b-b1f5-5ee48dd6378d' | System | 11 Oct 2020 18:12:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Oct 2020 18:12:16 |

US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-11T14:11:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0455e469-17bd-470b-b1f5-5ee48dd6378d' User entered 'No (N)' | System | 11 Oct 2020 18:12:16 |
|                                                                                                                                                                                                                                                                                      | System | 11 Oct 2020 18:12:16 |

US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-11T14:11:55', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0455e469-17bd-470b-b1f5-5ee48dd6378d' User entered 'No (N)' | System | 11 Oct 2020 18:12:16 |
|                                                                                                                                                                                                                                                                                      | System | 11 Oct 2020 18:12:16 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-11T14:12:12', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0455e469-17bd-470b-b1f5-5ee48dd6378d' User entered '11 Oct 2020 14:12:12' | System | 11 Oct 2020 18:12:16 |
|                                                                                                                                                                                                                                                                                                    | System | 11 Oct 2020 18:12:16 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '07 Oct 2020 00:01' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '11 Oct 2020 23:59' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 71' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-14T00:02:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0818cd38-616f-453c-8d73-3d7d7e2cfdbe' User entered 'No (N)' | System | 14 Oct 2020 04:02:43 |
|                                                                                                                                                                                                                                                                                      | System | 14 Oct 2020 04:02:43 |



**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-14T00:02:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0818cd38-616f-453c-8d73-3d7d7e2cfdbe' User entered 'No (N)' | System | 14 Oct 2020 04:02:43 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-14T00:02:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0818cd38-616f-453c-8d73-3d7d7e2cfdbe' User entered '14 Oct 2020 00:02:39' | System | 14 Oct 2020 04:02:43 |
|                                                                                                                                                                                                                                                                                                    | System | 14 Oct 2020 04:02:43 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '14 Oct 2020 00:01' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '18 Oct 2020 23:59' | System | 07 Aug 2020 18:14:44 |

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:35

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 78' | System | 07 Aug 2020 18:14:44 |

US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:12:07', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777' | System | 24 Oct 2020 03:12:47 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 24 Oct 2020 03:12:47 |

US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:11:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777' | System | 24 Oct 2020 03:12:47 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Oct 2020 03:12:47 |

US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:11:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777' | System | 24 Oct 2020 03:12:47 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Oct 2020 03:12:47 |



US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:11:30', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777' | System | 24 Oct 2020 03:12:47 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 24 Oct 2020 03:12:47 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:11:45', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777' | System | 24 Oct 2020 03:12:47 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'                                                                                                                                                               | System | 24 Oct 2020 03:12:47 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:12:23', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777' | System | 24 Oct 2020 03:12:47 |
| User entered '23 Oct 2020 23:12:23'                                                                                                                                                                                                                            | System | 24 Oct 2020 03:12:47 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '21 Oct 2020 00:01' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '25 Oct 2020 23:59' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 92' | System | 07 Aug 2020 18:14:44 |

US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-07T01:47:41', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c3710cf0-5ce6-4e2a-98f3-db327a2e5a38' | System | 07 Nov 2020 06:48:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Nov 2020 06:48:25 |

US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-07T01:47:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c3710cf0-5ce6-4e2a-98f3-db327a2e5a38' | System | 07 Nov 2020 06:48:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Nov 2020 06:48:25 |



**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-07T01:48:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c3710cf0-5ce6-4e2a-98f3-db327a2e5a38' User entered '07 Nov 2020 01:48:21' | System | 07 Nov 2020 06:48:25 |
|                                                                                                                                                                                                                                                                                                    | System | 07 Nov 2020 06:48:25 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '04 Nov 2020 00:01' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '08 Nov 2020 23:59' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 99' | System | 07 Aug 2020 18:14:44 |

US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-11T00:04:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '4057d283-1463-477c-bbb8-821009dc15c2' | System | 11 Nov 2020 05:04:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Nov 2020 05:04:26 |

US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-11T00:04:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '4057d283-1463-477c-bbb8-821009dc15c2' | System | 11 Nov 2020 05:04:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 11 Nov 2020 05:04:26 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-11T00:04:20', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '4057d283-1463-477c-bbb8-821009dc15c2' | System | 11 Nov 2020 05:04:26 |
| User entered '11 Nov 2020 00:04:20'                                                                                                                                                                                                                            | System | 11 Nov 2020 05:04:26 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '11 Nov 2020 00:01' | System | 07 Aug 2020 18:14:44 |



**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '15 Nov 2020 23:59' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                  | User   | Time (GMT)           |
|------------------------|--------|----------------------|
| Data entry locked.     | System | 07 Aug 2020 18:14:44 |
| User entered 'Day 106' | System | 07 Aug 2020 18:14:44 |

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-18T00:01:49', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9a9020ca-f944-4992-8ded-3ae777acfd2f' User entered 'No (N)' | System | 18 Nov 2020 05:02:14 |

US3822043

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-18T00:02:01', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9a9020ca-f944-4992-8ded-3ae777acfd2f' User entered 'No (N)' | System | 18 Nov 2020 05:02:14 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-18T00:02:07', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9a9020ca-f944-4992-8ded-3ae777acfd2f' User entered '18 Nov 2020 00:02:07' | System | 18 Nov 2020 05:02:14 |
|                                                                                                                                                                                                                                                                                                    | System | 18 Nov 2020 05:02:14 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '18 Nov 2020 00:01' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 07 Aug 2020 18:14:44 |
| User entered '22 Nov 2020 23:59' | System | 07 Aug 2020 18:14:44 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '04 Oct 2020 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '08 Oct 2020 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '11 Oct 2020 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '15 Oct 2020 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '18 Oct 2020 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '22 Oct 2020 23:59' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '25 Oct 2020 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '29 Oct 2020 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '01 Nov 2020 00:01' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '05 Nov 2020 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '08 Nov 2020 00:01' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '12 Nov 2020 23:59' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-19T21:58:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '850d0509-70fa-47bb-a6f9-4c5ee3e648ff' | System | 20 Nov 2020 02:58:43 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Nov 2020 02:58:43 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-19T21:58:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '850d0509-70fa-47bb-a6f9-4c5ee3e648ff' User entered 'No (N)' | System | 20 Nov 2020 02:58:43 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-19T21:58:37', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '850d0509-70fa-47bb-a6f9-4c5ee3e648ff' User entered '19 Nov 2020 21:58:37' | System | 20 Nov 2020 02:58:43 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '15 Nov 2020 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '19 Nov 2020 23:59' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-22T00:01:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3aaeb1ad-b24e-4a11-8a00-9c7ad152dbfa' User entered 'No (N)' | System | 22 Nov 2020 05:02:48 |
|                                                                                                                                                                                                                                                                                      | System | 22 Nov 2020 05:02:48 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-22T00:01:40', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3aaeb1ad-b24e-4a11-8a00-9c7ad152dbfa' User entered 'No (N)' | System | 22 Nov 2020 05:02:48 |

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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-22T00:01:50', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3aaeb1ad-b24e-4a11-8a00-9c7ad152dbfa' User entered '22 Nov 2020 00:01:50' | System | 22 Nov 2020 05:02:48 |
|                                                                                                                                                                                                                                                                                                    | System | 22 Nov 2020 05:02:48 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '22 Nov 2020 00:01' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '26 Nov 2020 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '29 Nov 2020 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '03 Dec 2020 23:59' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 15:56:28 |

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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 15:56:28 |
| Amendment Manager: User entered '06 Dec 2020 00:01' | System | 19 Nov 2020 15:56:28 |

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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 15:56:28 |
| Amendment Manager: User entered '10 Dec 2020 23:59' | System | 19 Nov 2020 15:56:28 |

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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 15:56:28 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '13 Dec 2020 00:01' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '17 Dec 2020 23:59' | System | 19 Nov 2020 15:56:28 |

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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 15:56:28 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 15:56:28 |

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[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '20 Dec 2020 00:01' | System | 19 Nov 2020 15:56:28 |



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[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '24 Dec 2020 23:59' | System | 19 Nov 2020 15:56:28 |

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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 15:56:28 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 15:56:28 |

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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 15:56:28 |
| Amendment Manager: User entered '27 Dec 2020 00:01' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '31 Dec 2020 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '03 Jan 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '07 Jan 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '10 Jan 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '14 Jan 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '17 Jan 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '21 Jan 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '24 Jan 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '28 Jan 2021 23:59' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '31 Jan 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '04 Feb 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '07 Feb 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '11 Feb 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '14 Feb 2021 00:01' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '18 Feb 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '21 Feb 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '25 Feb 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '28 Feb 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '04 Mar 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '07 Mar 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '11 Mar 2021 23:59' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '14 Mar 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '18 Mar 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '21 Mar 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '25 Mar 2021 23:59' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '28 Mar 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '01 Apr 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**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 15:56:28 |
| Amendment Manager: User entered '04 Apr 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '08 Apr 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '11 Apr 2021 00:01' | System | 19 Nov 2020 15:56:28 |



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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '15 Apr 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '18 Apr 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '22 Apr 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '25 Apr 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '29 Apr 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '02 May 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '06 May 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '09 May 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '13 May 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '16 May 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '20 May 2021 23:59' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '23 May 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '27 May 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '30 May 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '03 Jun 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '06 Jun 2021 00:01' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '10 Jun 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '13 Jun 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '17 Jun 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '20 Jun 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '24 Jun 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '27 Jun 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '01 Jul 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '04 Jul 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '08 Jul 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '11 Jul 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '15 Jul 2021 23:59' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '18 Jul 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '22 Jul 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '25 Jul 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '29 Jul 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '01 Aug 2021 00:01' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '05 Aug 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '08 Aug 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '12 Aug 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '15 Aug 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '19 Aug 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '22 Aug 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '26 Aug 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '29 Aug 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '02 Sep 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '05 Sep 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '09 Sep 2021 23:59' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '12 Sep 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '16 Sep 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '19 Sep 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '23 Sep 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '26 Sep 2021 00:01' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '30 Sep 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '03 Oct 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '07 Oct 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '10 Oct 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '14 Oct 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '17 Oct 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '21 Oct 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '24 Oct 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '28 Oct 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '31 Oct 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '04 Nov 2021 23:59' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '07 Nov 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '11 Nov 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '14 Nov 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '18 Nov 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '21 Nov 2021 00:01' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '25 Nov 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '28 Nov 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '02 Dec 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '05 Dec 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '09 Dec 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '12 Dec 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '16 Dec 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '19 Dec 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '23 Dec 2021 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '26 Dec 2021 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '30 Dec 2021 23:59' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '02 Jan 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '06 Jan 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '09 Jan 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '13 Jan 2022 23:59' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '16 Jan 2022 00:01' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '20 Jan 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '23 Jan 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '27 Jan 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '30 Jan 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '03 Feb 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '06 Feb 2022 00:01' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '10 Feb 2022 23:59' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '13 Feb 2022 00:01' | System | 19 Nov 2020 15:56:28 |

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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 15:56:28 |
| Amendment Manager: User entered '17 Feb 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**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 15:56:28 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '20 Feb 2022 00:01' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '24 Feb 2022 23:59' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '27 Feb 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '03 Mar 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '06 Mar 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '10 Mar 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '13 Mar 2022 00:01' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '17 Mar 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '20 Mar 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '24 Mar 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '27 Mar 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '31 Mar 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '03 Apr 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '07 Apr 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '10 Apr 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '14 Apr 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '17 Apr 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '21 Apr 2022 23:59' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '24 Apr 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '28 Apr 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '01 May 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '05 May 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '08 May 2022 00:01' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '12 May 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '15 May 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '19 May 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '22 May 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '26 May 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '29 May 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '02 Jun 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '05 Jun 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '09 Jun 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '12 Jun 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '16 Jun 2022 23:59' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '19 Jun 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '23 Jun 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '26 Jun 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '30 Jun 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '03 Jul 2022 00:01' | System | 19 Nov 2020 15:56:28 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '07 Jul 2022 23:59' | System | 19 Nov 2020 15:56:28 |

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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 15:56:28 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 15:56:28 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '10 Jul 2022 00:01' | System | 19 Nov 2020 15:56:28 |

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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 15:56:28 |
| Amendment Manager: User entered '14 Jul 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '17 Jul 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '21 Jul 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '24 Jul 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '28 Jul 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '31 Jul 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '04 Aug 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '07 Aug 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '11 Aug 2022 23:59' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '14 Aug 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '18 Aug 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '21 Aug 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '25 Aug 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '28 Aug 2022 00:01' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '01 Sep 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '04 Sep 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '08 Sep 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '11 Sep 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '15 Sep 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '18 Sep 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '22 Sep 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '25 Sep 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '29 Sep 2022 23:59' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '02 Oct 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '06 Oct 2022 23:59' | System | 19 Nov 2020 15:56:28 |



**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '09 Oct 2022 00:01' | System | 19 Nov 2020 15:56:28 |

**US3822043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:55:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 15:56:28 |
| Amendment Manager: User entered '13 Oct 2022 23:59' | System | 19 Nov 2020 15:56:28 |

US3822043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Was Contact Attempted?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 29 Oct 2020 19:49:40 |

US3822043

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:55:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User entered '29 Oct 2020' | Krishna Shah (b) (4)<br>(b) (4) | 29 Oct 2020 19:49:40 |

US3822043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Please select one status for the follow-up contact](#)

| Audit                                      | User                            | Time (GMT)           |
|--------------------------------------------|---------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Krishna Shah (b) (4)<br>(b) (4) | 29 Oct 2020 19:49:40 |

US3822043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:35

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Krishna Shah (b) (4)<br>(b) (4) | 29 Oct 2020 19:49:40 |

US3822043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:35

[Is the participant continuing to the next visit?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Krishna Shah (b) (4)<br>(b) (4) | 29 Oct 2020 19:49:45 |



US3822043

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:55:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Oct 2020 19:49:45 |

US3822043

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:55:35

[Did the participant experience any adverse events?](#)

| Audit                                                                                                                  | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Please confirm Yes, as Adverse Events are included in EDC.' (Site from CRA). DataPoint Verified.    | (b) (4), (b) (6)      | 19 Nov 2020 13:50:16 |
|                                                                                                                        | (b) (4), (b) (6)      | 19 Nov 2020 13:50:10 |
| Query 'Please confirm Yes, as Adverse Events are included in EDC.' answered with 'updated' (Site from CRA).            | Krishna Shah (b) (4)  | 18 Nov 2020 21:26:10 |
|                                                                                                                        | (b) (4)               |                      |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                             | Krishna Shah (b) (4)  | 18 Nov 2020 21:26:04 |
|                                                                                                                        | (b) (4)               |                      |
| User opened query 'Please confirm Yes, as Adverse Events are included in EDC.' (Site from CRA). DataPoint Un-verified. | (b) (4), (b) (6)      | 17 Nov 2020 19:57:20 |
|                                                                                                                        | (b) (4), (b) (6)      | 17 Nov 2020 19:56:37 |
| DataPoint Verified.                                                                                                    | (b) (4), (b) (6)      | 17 Nov 2020 19:56:19 |
|                                                                                                                        | (b) (4), (b) (6)      |                      |
| User entered 'No (N)' reason for change: Data Entry Error                                                              | (b) (4), (b) (6)      | 20 Oct 2020 15:08:00 |
|                                                                                                                        | (b) (4)               |                      |
| User entered 'Yes (Y)'                                                                                                 | Kelly Woodell (b) (4) | 26 Aug 2020 02:07:33 |
|                                                                                                                        | (b) (4)               |                      |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 18 Nov 2020 14:43:21 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 26 Oct 2020 20:56:33 |
| User entered<br>'USA-US126-2020-mRNA-1273-P301000006' | System           | 26 Oct 2020 20:56:27 |
| User entered 'New'                                    | (b) (4), (b) (6) | 26 Oct 2020 20:56:27 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Adverse event](#)

| Audit                                                                                                                                                                                                                                                                                 | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)      | 18 Nov 2020 14:43:23 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Lymphomas non-Hodgkin's B-cell, HLT: B-cell small lymphocytic lymphomas, PT: B-cell small lymphocytic lymphoma, LLT: Small cell lymphocytic lymphoma - version MedDRA\\23.0. | Coder Import (b) (4)  | 23 Oct 2020 21:46:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                                                               | (b) (4)               | 23 Oct 2020 21:46:40 |
| Data point term sent to Coder                                                                                                                                                                                                                                                         | System                | 23 Oct 2020 17:37:29 |
| User entered 'Small Lymphocytic lymphoma'                                                                                                                                                                                                                                             | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |
|                                                                                                                                                                                                                                                                                       | (b) (4)               |                      |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Was this a medically-attended AE?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 18 Nov 2020 14:43:25 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 18 Nov 2020 14:43:27 |
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:37:27 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 18 Nov 2020 14:43:29 |
| User entered 'No (N)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |
|                       | (b) (4)               |                      |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 18 Nov 2020 14:43:33 |
| User entered '06 Oct 2020' | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |



US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

Start time (00:00-23:59)

| Audit                                                                                                                                                                                                                         | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                                                        | (b) (4), (b) (6)     | 24 Nov 2020 14:25:11 |
| User closed query 'Please enter data into EDC if applicable.' (Site from CRA).                                                                                                                                                | (b) (4), (b) (6)     | 23 Nov 2020 20:50:45 |
| DataPoint Verified.                                                                                                                                                                                                           | (b) (4), (b) (6)     | 23 Nov 2020 20:50:42 |
| Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Keep getting asked to provide time and remove time. Which do I do?' (Site from System). | (b) (4), (b) (6)     | 23 Nov 2020 13:48:18 |
| Query 'Please enter data into EDC if applicable.' answered with 'updated' (Site from CRA).                                                                                                                                    | (b) (4), (b) (6)     | 23 Nov 2020 13:47:33 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                                                        | System               | 23 Nov 2020 13:47:25 |
| User entered '11:00' reason for change: Data Entry Error                                                                                                                                                                      | (b) (4), (b) (6)     | 23 Nov 2020 13:47:25 |
| User opened query 'Please enter data into EDC if applicable.' (Site from CRA).                                                                                                                                                | (b) (4), (b) (6)     | 19 Nov 2020 13:48:56 |
| User closed query 'Per CRIO source, 11:00 is noted. Please reconcile and update if applicable.' (Site from CRA).                                                                                                              | (b) (4), (b) (6)     | 19 Nov 2020 13:48:56 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                                                        | System               | 18 Nov 2020 21:16:43 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                        | Krishna Shah (b) (4) | 18 Nov 2020 21:16:43 |
| Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Time was entered per previous query. Time is removed again.' (Site from System).        | Krishna Shah (b) (4) | 18 Nov 2020 21:16:22 |
| Query 'Per CRIO source, 11:00 is noted. Please reconcile and update if applicable.' answered with 'updated' (Site from CRA).                                                                                                  | Krishna Shah (b) (4) | 18 Nov 2020 21:15:42 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                                                        | System               | 18 Nov 2020 21:15:30 |
| User entered '11:00' reason for change: Data Entry Error                                                                                                                                                                      | Krishna Shah (b) (4) | 18 Nov 2020 21:15:30 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Start time \(00:00-23:59\)](#)

| Audit                                                                                                            | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User opened query 'Per CRIO source, 11:00 is noted. Please reconcile and update if applicable.' (Site from CRA). | (b) (4), (b) (6)      | 18 Nov 2020 14:44:10 |
| User entered empty.                                                                                              | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[AE start date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 11:00' | System | 23 Nov 2020 13:47:25 |
| User entered empty.              | System | 18 Nov 2020 21:16:43 |
| User entered '06 Oct 2020 11:00' | System | 18 Nov 2020 21:15:30 |
| User entered empty.              | System | 23 Oct 2020 17:37:27 |

**US3822043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 18 Nov 2020 14:44:16 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                                                                | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).                                                                                                                                          | (b) (4), (b) (6)                 | 24 Nov 2020 19:28:15 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'not yet recovered' (Site from Safety).                                                                                                                    | (b) (4), (b) (6)                 | 23 Nov 2020 13:48:28 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6)                 | 18 Nov 2020 14:44:30 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).                                                                                                                                          | (b) (4), (b) (6)                 | 13 Nov 2020 23:27:25 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).                                                                                                                                          | (b) (4), (b) (6)                 | 06 Nov 2020 15:38:51 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Subject has not followed up with oncology since 10/21/2020. At this time no treatment has been given therefore SAE is still ongoing.' (Site from Safety). | Kelly Woodell (b) (4)<br>(b) (4) | 04 Nov 2020 15:38:32 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).                                                                                                                                          | (b) (4), (b) (6)                 | 02 Nov 2020 18:01:37 |
| User entered empty.                                                                                                                                                                                                                                                                                                                                  | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:37:27 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

End time (00:00-23:59)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:44:34 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

**US3822043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 09:55:35**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Oct 2020 17:37:27 |

**US3822043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Severity](#)

| Audit                                          | User                             | Time (GMT)           |
|------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)                 | 18 Nov 2020 14:44:37 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:37:27 |



US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Is the adverse event serious?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 18 Nov 2020 14:44:39 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

**US3822043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Death](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:10 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Life threatening](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:12 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

**US3822043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:13 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |
|                     | (b) (4)               |                      |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:15 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

Hospital Discharge Date (dd MMM yyyy)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:17 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

**US3822043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Admitted to ICU?](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:21 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Number of Days in ICU](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:22 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |
|                     | (b) (4)               |                      |



US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Persistent or significant disability or incapacity](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:24 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Congenital anomaly or birth defect](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:33 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Other medically important event](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:36 |
| User entered '1'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Relationship to investigational product](#)

| Audit                                                                                                                                                                                                                           | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                             | (b) (4), (b) (6)                 | 18 Nov 2020 14:45:37 |
| User closed query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).                                                                             | (b) (4), (b) (6)                 | 06 Nov 2020 15:38:54 |
| Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' answered with 'PI rationale is that the even was diagnosed a month after 2nd injection' (Site from Safety). | Kelly Woodell (b) (4)<br>(b) (4) | 04 Nov 2020 15:49:05 |
| User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).                                                                             | (b) (4), (b) (6)                 | 02 Nov 2020 18:00:43 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                                      | System                           | 27 Oct 2020 12:31:16 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                                                                                                                                          | System                           | 27 Oct 2020 12:31:16 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error                                                                                                                                                            | Kelly Woodell (b) (4)<br>(b) (4) | 27 Oct 2020 12:31:16 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                                      | System                           | 23 Oct 2020 17:37:27 |
| User entered empty.                                                                                                                                                                                                             | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:37:27 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Relationship to Study Procedure](#)

| Audit                                                                                                                                                                                                         | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                           | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:14 |
| User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.<br>' (Site from DM).              | (b) (4), (b) (6)                 | 19 Nov 2020 15:10:59 |
| Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.<br>' answered with 'updated ' (Site from DM). | Krishna Shah (b) (4)<br>(b) (4)  | 18 Nov 2020 21:23:18 |
| DataPoint Un-verified.                                                                                                                                                                                        | Krishna Shah (b) (4)<br>(b) (4)  | 18 Nov 2020 21:23:05 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error                                                                                                                                          | Krishna Shah (b) (4)<br>(b) (4)  | 18 Nov 2020 21:23:05 |
| DataPoint Verified.                                                                                                                                                                                           | (b) (4), (b) (6)                 | 18 Nov 2020 14:45:42 |
| User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.<br>' (Site from DM).              | (b) (4), (b) (6)                 | 18 Nov 2020 08:04:04 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                    | System                           | 27 Oct 2020 12:31:16 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                                                                                                                        | System                           | 27 Oct 2020 12:31:16 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error                                                                                                                            | Kelly Woodell (b) (4)<br>(b) (4) | 27 Oct 2020 12:31:16 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                    | System                           | 23 Oct 2020 17:37:27 |
| User entered empty.                                                                                                                                                                                           | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:37:27 |

**US3822043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Action taken with investigational product](#)

| Audit                                          | User                  | Time (GMT)           |
|------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)      | 18 Nov 2020 14:45:46 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[None](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:50 |
| User entered '1'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Concomitant Medication](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:52 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Concomitant Procedure](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:45:55 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Outcome](#)

| Audit                                                                                                                                                                                                                                                                                                            | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| 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)      | 24 Nov 2020 19:28:26 |
| 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 'This is not expected to have a resolution date in the near future. ' (Site from Safety). | Krishna Shah (b) (4)  | 23 Nov 2020 17:39:47 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)      | 18 Nov 2020 14:45:57 |
| 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) (6)      | 13 Nov 2020 23:25:59 |
| 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)      | 06 Nov 2020 15:38:56 |
| 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 'Outcome is correct as is' (Site from Safety).                                            | Kelly Woodell (b) (4) | 04 Nov 2020 15:47:53 |
| 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) (6)      | 02 Nov 2020 18:00:04 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'                                                                                                                                                                                                                                           | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 09:55:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 18 Nov 2020 14:46:02 |
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:37:27 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                         | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).                                                   | (b) (4), (b) (6) | 24 Nov 2020 19:28:30 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No treatment was provided' (Site from Safety). DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:29:30 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).                                                   | (b) (4), (b) (6) | 18 Nov 2020 14:46:25 |
| User closed query 'PV Query: Please report if the patient has any risk factors for small cell lymphocytic lymphoma.' (Site from Safety).                                                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 13 Nov 2020 23:26:38 |
| User closed query 'PV Query: Has the subject seen an oncologist or have a future appointment scheduled?' (Site from Safety).                                                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 06 Nov 2020 15:39:04 |
| User closed query 'PV Query: Please provide the date of biopsy.' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6) | 06 Nov 2020 15:39:03 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 06 Nov 2020 15:39:02 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).                                          | (b) (4), (b) (6)      | 06 Nov 2020 15:39:00 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test (i.e. additional scans) results. Please include units and reference ranges if applicable.' (Site from Safety).                                                                                                                                                                                                                               | (b) (4), (b) (6)      | 06 Nov 2020 15:38:58 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test (i.e. additional scans) results. Please include units and reference ranges if applicable.' answered with 'All diagnostic test have been added to the concomitant procedure page' (Site from Safety).                                                                                                                                                     | Kelly Woodell (b) (4) | 04 Nov 2020 15:50:54 |
| Query 'PV Query: Please report if the patient has any risk factors for small cell lymphocytic lymphoma.' answered with 'There were no risk factors known' (Site from Safety).                                                                                                                                                                                                                                                        | Kelly Woodell (b) (4) | 04 Nov 2020 15:50:31 |
| Query 'PV Query: Has the subject seen an oncologist or have a future appointment scheduled?' answered with 'The subject has seen an oncologist. Records will be submitted today to safety.' (Site from Safety).                                                                                                                                                                                                                      | Kelly Woodell (b) (4) | 04 Nov 2020 15:50:09 |
| Query 'PV Query: Please provide the date of biopsy.' answered with 'Biopsy date is recorded on concomitant procedures page' (Site from Safety).                                                                                                                                                                                                                                                                                      | Kelly Woodell (b) (4) | 04 Nov 2020 15:49:49 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No treatment or plan have been given' (Site from Safety). | Kelly Woodell (b) (4) | 04 Nov 2020 15:48:14 |
| User opened query 'PV Query: Please report if the patient has any risk factors for small cell lymphocytic lymphoma.' (Site from Safety).                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)      | 02 Nov 2020 18:02:43 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:55:35

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                       | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User opened query 'PV Query: Has the subject seen an oncologist or have a future appointment scheduled?' (Site from Safety).                                                                                                                                                                                                                                                                | (b) (4), (b) (6)      | 02 Nov 2020 18:02:27 |
| User opened query 'PV Query: Please provide the date of biopsy.' (Site from Safety).                                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)      | 02 Nov 2020 18:02:09 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6)      | 02 Nov 2020 18:00:22 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test (i.e. additional scans) results. Please include units and reference ranges if applicable.' (Site from Safety).                                                                                                                                                                                      | (b) (4), (b) (6)      | 02 Nov 2020 17:59:19 |
| User entered 'The patient was scheduled for routine CT of the chest to screen for lung cancer on 9/5/2020. The CT showed an enlarged let axillary lymph node that was new since 6/26/2018. Due to the findings the subject was scheduled for an ultrasound guided biopsy. The biopsy results were small lymphocytic lymphoma.'                                                              | Kelly Woodell (b) (4) | 23 Oct 2020 17:37:27 |

US3822043

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:55:35

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Oct 2020 17:37:27 |

US3822043

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:55:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Oct 2020 17:37:27 |



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Adverse event](#)

| Audit                                                                                                                                                                                                                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                        | (b) (4), (b) (6)                 | 18 Nov 2020 14:46:53 |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Axillary lymph nodes enlarged - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 23 Oct 2020 22:42:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                                    | Coder Import (b) (4)<br>(b) (4)  | 23 Oct 2020 22:42:37 |
| Data point term sent to Coder                                                                                                                                                                                                                              | System                           | 23 Oct 2020 17:42:53 |
| User entered 'Enlarged left axillary lymph nodes'                                                                                                                                                                                                          | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Was this a medically-attended AE?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 18 Nov 2020 14:46:57 |
| User entered 'Yes (Y)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 18 Nov 2020 14:46:59 |
| User entered 'No (N)' | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 18 Nov 2020 14:47:01 |
| User entered 'No (N)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 18 Nov 2020 14:47:04 |
| User entered '5 Sep 2020' | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

Start time (00:00-23:59)

| Audit                                                                                                                                                                                                                                                                               | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)                 | 23 Nov 2020 20:51:51 |
| User closed query 'Please re-review CRIO ad update Start Time if applicable. Data entry time is 15:29 vs. AE start time is noted as 13:06. Please reconcile and update if applicable.' (Site from CRA).                                                                             | (b) (4), (b) (6)                 | 23 Nov 2020 20:51:49 |
| Query 'Please re-review CRIO ad update Start Time if applicable. Data entry time is 15:29 vs. AE start time is noted as 13:06. Please reconcile and update if applicable.' answered with 'START TIME IS NOT REQUIRED SINCE IT DID NOT START WITHIN 24 HOURS OF IP' (Site from CRA). | (b) (4), (b) (6)                 | 23 Nov 2020 14:10:44 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                                                                                                              | System                           | 23 Nov 2020 14:10:35 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                                                                              | (b) (4), (b) (6)                 | 23 Nov 2020 14:10:35 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                                                                                                              | System                           | 23 Nov 2020 14:09:49 |
| User entered '13:06' reason for change: Data Entry Error                                                                                                                                                                                                                            | (b) (4), (b) (6)                 | 23 Nov 2020 14:09:49 |
| User opened query 'Please re-review CRIO ad update Start Time if applicable. Data entry time is 15:29 vs. AE start time is noted as 13:06. Please reconcile and update if applicable.' (Site from CRA).                                                                             | (b) (4), (b) (6)                 | 19 Nov 2020 18:48:40 |
| User closed query 'Per CRIO source, start time is 13:06. Please reconcile and update if applicable.' (Site from CRA).                                                                                                                                                               | (b) (4), (b) (6)                 | 19 Nov 2020 18:48:40 |
| Query 'Per CRIO source, start time is 13:06. Please reconcile and update if applicable.' answered with 'That was the time of data entry not a start time. Time unknown.' (Site from CRA).                                                                                           | Krishna Shah (b) (4)<br>(b) (4)  | 18 Nov 2020 21:24:24 |
| User opened query 'Per CRIO source, start time is 13:06. Please reconcile and update if applicable.' (Site from CRA).                                                                                                                                                               | (b) (4), (b) (6)                 | 18 Nov 2020 14:47:38 |
| User entered empty.                                                                                                                                                                                                                                                                 | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[AE start date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered empty.             | System | 23 Nov 2020 14:10:35 |
| User entered '5 Sep 2020 13:06' | System | 23 Nov 2020 14:09:49 |
| User entered empty.             | System | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Ongoing?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 18 Nov 2020 14:47:50 |
| User entered 'No (N)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |



US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 18 Nov 2020 14:47:52 |
| User entered '06 Oct 2020' | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |
|                            | (b) (4)               |                      |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

End time (00:00-23:59)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:47:56 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Severity](#)

| Audit                                                                                                                        | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                          | (b) (4), (b) (6)                 | 19 Nov 2020 17:24:49 |
| User closed query 'Per CRIO. Severity is Moderate. Please reconcile and update if applicable.' (Site from CRA).              | (b) (4), (b) (6)                 | 19 Nov 2020 17:24:43 |
| Query 'Per CRIO. Severity is Moderate. Please reconcile and update if applicable.' answered with 'updated ' (Site from CRA). | Krishna Shah (b) (4)<br>(b) (4)  | 18 Nov 2020 21:24:48 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error                                       | Krishna Shah (b) (4)<br>(b) (4)  | 18 Nov 2020 21:24:41 |
| User opened query 'Per CRIO. Severity is Moderate. Please reconcile and update if applicable.' (Site from CRA).              | (b) (4), (b) (6)                 | 18 Nov 2020 14:48:32 |
| User entered 'Grade 3/Severe (Grade 3/Severe)'                                                                               | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Is the adverse event serious?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 18 Nov 2020 14:48:46 |
| User entered 'No (N)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Death](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:48:48 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Life threatening](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:48:49 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:48:51 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |
|                     | (b) (4)               |                      |



US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:48:53 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

Hospital Discharge Date (dd MMM yyyy)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:48:55 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Admitted to ICU?](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:49:47 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Number of Days in ICU](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:49:48 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Persistent or significant disability or incapacity](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:49:50 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Congenital anomaly or birth defect](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:49:52 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Other medically important event](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:49:55 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Relationship to investigational product](#)

| Audit                                                                                  | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)      | 18 Nov 2020 14:49:58 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                | 27 Oct 2020 12:31:49 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 27 Oct 2020 12:31:49 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error                   | Kelly Woodell (b) (4) | 27 Oct 2020 12:31:49 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 23 Oct 2020 17:42:40 |
| User entered empty.                                                                    | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |



US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Relationship to Study Procedure](#)

| Audit                                                                                                                                                                                                                    | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                      | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:14 |
| User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.<br>' (Site from DM).                         | (b) (4), (b) (6)                 | 19 Nov 2020 15:11:18 |
| Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.<br>' answered with 'updated per source.' (Site from DM). | Krishna Shah (b) (4)<br>(b) (4)  | 18 Nov 2020 21:25:18 |
| DataPoint Un-verified.                                                                                                                                                                                                   | Krishna Shah (b) (4)<br>(b) (4)  | 18 Nov 2020 21:25:10 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error                                                                                                                                                     | Krishna Shah (b) (4)<br>(b) (4)  | 18 Nov 2020 21:25:10 |
| DataPoint Verified.                                                                                                                                                                                                      | (b) (4), (b) (6)                 | 18 Nov 2020 14:50:04 |
| User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.<br>' (Site from DM).                         | (b) (4), (b) (6)                 | 18 Nov 2020 08:03:45 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                               | System                           | 27 Oct 2020 12:31:49 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                                                                                                                                   | System                           | 27 Oct 2020 12:31:49 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error                                                                                                                                       | Kelly Woodell (b) (4)<br>(b) (4) | 27 Oct 2020 12:31:49 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                               | System                           | 23 Oct 2020 17:42:40 |
| User entered empty.                                                                                                                                                                                                      | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Action taken with investigational product](#)

| Audit                                          | User                  | Time (GMT)           |
|------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)      | 18 Nov 2020 14:50:18 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

**US3822043**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 09:55:35**

[None](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:50:40 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Concomitant Medication](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:50:42 |
| User entered '0'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

[Concomitant Procedure](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 14:50:47 |
| User entered '1'    | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

**US3822043**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Outcome](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 18 Nov 2020 14:50:49 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:55:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 18 Nov 2020 14:50:53 |
| User entered empty. | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:42:40 |

**US3822043**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Narrative](#)

| Audit                                                                | User                  | Time (GMT)           |
|----------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                  | (b) (4), (b) (6)      | 18 Nov 2020 14:50:55 |
| User entered 'Subject was scheduled for an ultrasound guided biopsy' | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:40 |



**US3822043**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 23 Oct 2020 17:42:40 |

US3822043

**Folder:** Adverse Events

**Form:** Adverse Events (4)

**Generated On:** 26 Nov 2020 09:55:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Oct 2020 17:42:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 09:55:35**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:24:13 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:29:01 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                     | User                                      | Time (GMT)                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------------------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CALCIUM<br>CHANNEL BLOCKERS, ATC: SELECTIVE<br>CALCIUM CHANNEL BLOCKERS WITH<br>MAINLY VASCULAR EFFECTS, ATC:<br>DIHYDROPYRIDINE DERIVATIVES, PRODUCT:<br>AMLODIPINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)           | 18 Nov 2020 21:43:49                         |
| 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)           | 18 Nov 2020 21:43:49                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CALCIUM<br>CHANNEL BLOCKERS, ATC: SELECTIVE<br>CALCIUM CHANNEL BLOCKERS WITH<br>MAINLY VASCULAR EFFECTS, ATC:<br>DIHYDROPYRIDINE DERIVATIVES, PRODUCT:<br>AMLODIPINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)           | 18 Nov 2020 21:28:49                         |
| 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)           | 18 Nov 2020 21:28:49                         |
| Data point term sent to Coder<br>Coding entries removed.                                                                                                                                                                                                                  | System<br>Krishna Shah (b) (4)<br>(b) (4) | 18 Nov 2020 21:27:59<br>18 Nov 2020 21:27:17 |
| DataPoint Verified.                                                                                                                                                                                                                                                       | (b) (4), (b) (6)                          | 18 Nov 2020 16:33:47                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CALCIUM<br>CHANNEL BLOCKERS, ATC: SELECTIVE<br>CALCIUM CHANNEL BLOCKERS WITH<br>MAINLY VASCULAR EFFECTS, ATC:<br>DIHYDROPYRIDINE DERIVATIVES, PRODUCT:<br>AMLODIPINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)           | 06 Oct 2020 16:31:16                         |
| 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 Oct 2020 16:31:16                         |
| Data point term sent to Coder<br>User entered 'Amlodipine'                                                                                                                                                                                                                | System<br>(b) (4), (b) (6)                | 06 Oct 2020 16:30:09<br>06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:33:48 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:35

[Indication](#)

| Audit                                                                          | User                 | Time (GMT)           |
|--------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                            | (b) (4), (b) (6)     | 19 Nov 2020 13:50:47 |
| User closed query 'Please spell out Hypertension' (Site from CRA).             | (b) (4), (b) (6)     | 19 Nov 2020 13:50:41 |
| Query 'Please spell out Hypertension' answered with 'updated' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:27:22 |
| DataPoint Un-verified.                                                         | (b) (4)              |                      |
|                                                                                | Krishna Shah (b) (4) | 18 Nov 2020 21:27:17 |
|                                                                                | (b) (4)              |                      |
| User entered 'hypertension' reason for change: Data Entry Error                | Krishna Shah (b) (4) | 18 Nov 2020 21:27:17 |
|                                                                                | (b) (4)              |                      |
| DataPoint Verified.                                                            | (b) (4), (b) (6)     | 18 Nov 2020 16:33:50 |
|                                                                                | (b) (4), (b) (6)     |                      |
| User opened query 'Please spell out Hypertension' (Site from CRA).             | (b) (4), (b) (6)     | 18 Nov 2020 16:33:43 |
|                                                                                | (b) (4), (b) (6)     |                      |
| User entered 'HTN'                                                             | (b) (4), (b) (6)     | 06 Oct 2020 16:29:58 |
|                                                                                |                      |                      |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:33:52 |
| User entered '5'    | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:33:56 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:33:58 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:34:00 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:34:06 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:34:09 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:34:11 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:34:14 |
| User entered 'un UNK 2015' | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:34:16 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:34:17 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:34:21 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:34:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:29:58 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Oct 2020 16:29:58 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                             | User                            | Time (GMT)                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|
| 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: SIMVASTATIN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 18 Nov 2020 21:29:48                         |
| 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) | 18 Nov 2020 21:29:48                         |
| Data point term sent to Coder<br>Coding entries removed.                                                                                                                                                                          | System<br>Krishna Shah (b) (4)  | 18 Nov 2020 21:29:02<br>18 Nov 2020 21:28:31 |
| DataPoint Verified.                                                                                                                                                                                                               | (b) (4)<br>(b) (4), (b) (6)     | 18 Nov 2020 16:34:45                         |
| 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: SIMVASTATIN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:34:17                         |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.                                                                                                                   | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:34:17                         |
| Data point term sent to Coder<br>User entered 'Simvastatin'                                                                                                                                                                       | System<br>(b) (4), (b) (6)      | 06 Oct 2020 16:33:16<br>06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:34:47 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:35

[Indication](#)

| Audit                                                                                  | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)     | 19 Nov 2020 13:51:24 |
| User closed query 'Please spell out Hypercholesterolemia' (Site from CRA).             | (b) (4), (b) (6)     | 19 Nov 2020 13:51:19 |
| Query 'Please spell out Hypercholesterolemia' answered with 'updated' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:28:37 |
| User entered 'MIXED HYPERLIPIDEMIA' reason for change: Data Entry Error                | (b) (4)              | 18 Nov 2020 21:28:31 |
| User opened query 'Please spell out Hypercholesterolemia' (Site from CRA).             | Krishna Shah (b) (4) | 18 Nov 2020 16:35:31 |
| User entered 'HCL'                                                                     | (b) (4), (b) (6)     | 06 Oct 2020 16:32:31 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:35:39 |
| User entered '20'   | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:35:41 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:35:42 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:35:45 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:35:48 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:35:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:35:52 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:35:54 |
| User entered 'un UNK 2009' | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:35:56 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:36:00 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:36:04 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:36:06 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:32:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Oct 2020 16:32:31 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                           | User                            | Time (GMT)                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)                | 18 Nov 2020 16:36:20                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: DRUGS<br>FOR TREATMENT OF BONE DISEASES, ATC:<br>DRUGS AFFECTING BONE STRUCTURE AND<br>MINERALIZATION, ATC: OTHER DRUGS<br>AFFECTING BONE STRUCTURE AND<br>MINERALIZATION, PRODUCT: DENOSUMAB,<br>PRODUCTSYNONYM: PROLIA - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:34:17                         |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.                                                                                                                                                                                                                 | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:34:17                         |
| Data point term sent to Coder<br>User entered 'Prolia'                                                                                                                                                                                                                                                                          | System<br>(b) (4), (b) (6)      | 06 Oct 2020 16:33:17<br>06 Oct 2020 16:33:14 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:36:22 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                       | User             | Time (GMT)           |
|-----------------------------|------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6) | 18 Nov 2020 16:36:25 |
| User entered 'Osteoporosis' | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:36:33 |
| User entered '60'   | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:36:34 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |
|                     |                  |                      |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6) | 18 Nov 2020 16:36:36 |
| User entered 'other (OTHER)' | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit                         | User             | Time (GMT)           |
|-------------------------------|------------------|----------------------|
| DataPoint Verified.           | (b) (4), (b) (6) | 18 Nov 2020 16:36:42 |
| User entered 'every 6 months' | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 18 Nov 2020 16:36:44 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:36:47 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:36:50 |
| User entered 'UN UNK 2017' | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:36:52 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:36:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:36:58 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:36:59 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:33:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:33:14 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:33:14 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                       | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 23 Nov 2020 06:44:09 |
| 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) | 23 Nov 2020 06:44:09 |
| Data point term sent to Coder                                                                                                                                                                                                               | System                          | 18 Nov 2020 21:31:03 |
| Coding entries removed.                                                                                                                                                                                                                     | Krishna Shah (b) (4)<br>(b) (4) | 18 Nov 2020 21:30:31 |
| DataPoint Verified.                                                                                                                                                                                                                         | (b) (4), (b) (6)                | 18 Nov 2020 16:37:16 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:35:13 |
| 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 Oct 2020 16:35:13 |
| Data point term sent to Coder                                                                                                                                                                                                               | System                          | 06 Oct 2020 16:34:18 |
| User entered 'Ipratropium Bromide'                                                                                                                                                                                                          | (b) (4), (b) (6)                | 06 Oct 2020 16:34:07 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:35

[Prophylaxis](#)

| Audit                                                                                                                                          | User                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                            | (b) (4), (b) (6)     | 19 Nov 2020 13:51:50 |
| User closed query 'Per CRIO source, Prophylaxis is "Yes". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).             | (b) (4), (b) (6)     | 19 Nov 2020 13:51:43 |
| Query 'Per CRIO source, Prophylaxis is "Yes". Please reconcile and update CRIO or EDC as applicable.' answered with 'updated' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:30:36 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                                                     | (b) (4)              | 18 Nov 2020 21:30:31 |
| User opened query 'Per CRIO source, Prophylaxis is "Yes". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).             | (b) (4), (b) (6)     | 18 Nov 2020 16:38:04 |
| User entered 'No (N)'                                                                                                                          | (b) (4), (b) (6)     | 06 Oct 2020 16:34:07 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:35

[Indication](#)

| Audit                                                                                                                                                | User                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per CRIO source, Indication is "Supplement" Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).              | (b) (4), (b) (6)     | 19 Nov 2020 13:52:00 |
| DataPoint Verified.                                                                                                                                  | (b) (4), (b) (6)     | 19 Nov 2020 13:51:56 |
| Query 'Per CRIO source, Indication is "Supplement" Please reconcile and update CRIO or EDC as applicable.' answered with 'updated ' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:30:41 |
| User entered 'supplement' reason for change: Data Entry Error                                                                                        | (b) (4)              | 18 Nov 2020 21:30:31 |
| User opened query 'Per CRIO source, Indication is "Supplement" Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).              | (b) (4), (b) (6)     | 18 Nov 2020 16:39:12 |
| DataPoint Un-verified.                                                                                                                               | (b) (4), (b) (6)     | 18 Nov 2020 16:38:15 |
| DataPoint Verified.                                                                                                                                  | (b) (4), (b) (6)     | 18 Nov 2020 16:38:07 |
| User entered 'Allergies'                                                                                                                             | (b) (4), (b) (6)     | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:38:49 |
| User entered '42'   | (b) (4), (b) (6) | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:38:51 |
| User entered 'ug (ug)' | (b) (4), (b) (6) | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:38:58 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:34:07 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:35

[Frequency](#)

| Audit                                             | User                 | Time (GMT)           |
|---------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                               | (b) (4), (b) (6)     | 19 Nov 2020 13:52:07 |
| DataPoint Un-verified.                            | Krishna Shah (b) (4) | 18 Nov 2020 21:41:48 |
| User entered 'as needed (PRN)' reason for change: | (b) (4)              |                      |
| Data Entry Error                                  | Krishna Shah (b) (4) | 18 Nov 2020 21:41:48 |
| DataPoint Verified.                               | (b) (4)              |                      |
|                                                   | (b) (4), (b) (6)     | 18 Nov 2020 16:39:06 |
| User entered 'unknown (UNKNOWN)'                  | (b) (4), (b) (6)     | 06 Oct 2020 16:34:07 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit                                                                                                                                       | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per CRIO source, Frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).              | (b) (4), (b) (6)     | 19 Nov 2020 13:52:18 |
| DataPoint Verified.                                                                                                                         | (b) (4), (b) (6)     | 19 Nov 2020 13:52:15 |
| Query 'Per CRIO source, Frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated ' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:41:54 |
| User opened query 'Per CRIO source, Frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).              | (b) (4), (b) (6)     | 18 Nov 2020 16:39:38 |
| User entered empty.                                                                                                                         | (b) (4), (b) (6)     | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6) | 18 Nov 2020 16:39:41 |
| User entered 'Nasal (NASAL)' | (b) (4), (b) (6) | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:39:44 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:39:46 |
| User entered 'un UNK 2012' | (b) (4), (b) (6) | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:39:49 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:39:51 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:39:53 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:39:55 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:34:07 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:34:07 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:34:07 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                             | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                               | (b) (4), (b) (6)                | 18 Nov 2020 16:41:15 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 08 Oct 2020 04:46:24 |
| 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) | 08 Oct 2020 04:46:24 |
| Data point term sent to Coder                                                                                                                                                                     | System                          | 06 Oct 2020 16:36:19 |
| User entered 'Sertraline'                                                                                                                                                                         | (b) (4), (b) (6)                | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:41:17 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                                 | User             | Time (GMT)           |
|---------------------------------------|------------------|----------------------|
| DataPoint Verified.                   | (b) (4), (b) (6) | 18 Nov 2020 16:41:19 |
| User entered 'Depression and anxiety' | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:41:20 |
| User entered '50'   | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:41:22 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:41:25 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:41:26 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:41:29 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:41:31 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:41:34 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:41:37 |
| User entered 'un UNK 1997' | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:41:39 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:41:41 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:41:42 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:41:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:35:22 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Oct 2020 16:35:22 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                        | User                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                          | (b) (4), (b) (6)     | 18 Nov 2020 16:42:16 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Oct 2020 15:11:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                         | Coder Import (b) (4) | 07 Oct 2020 15:11:49 |
| Data point term sent to Coder                                                                                                                                                | System               | 06 Oct 2020 16:36:20 |
| User entered 'Lorazepam'                                                                                                                                                     | (b) (4), (b) (6)     | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:42:19 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                       | User             | Time (GMT)           |
|-----------------------------|------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6) | 18 Nov 2020 16:42:21 |
| User entered 'Restless leg' | (b) (4), (b) (6) | 06 Oct 2020 16:36:17 |



US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:35

[Dose per administration](#)

| Audit                                                                                                                                  | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                    | (b) (4), (b) (6)     | 19 Nov 2020 14:01:47 |
| User closed query 'Per CRIO source, Does is 1mg. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).              | (b) (4), (b) (6)     | 19 Nov 2020 14:01:43 |
| Query 'Per CRIO source, Does is 1mg. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated ' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:42:57 |
| User entered '1' reason for change: Data Entry Error                                                                                   | (b) (4)              | 18 Nov 2020 21:42:51 |
| User opened query 'Per CRIO source, Does is 1mg. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).              | (b) (4), (b) (6)     | 18 Nov 2020 16:42:51 |
| User entered '0.25'                                                                                                                    | (b) (4), (b) (6)     | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:42:54 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:42:56 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:43:00 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:43:01 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:43:04 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:43:06 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:36:17 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:35

Start date (dd MMM yyyy)

| Audit                                                                                                                                             | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                               | (b) (4), (b) (6)     | 19 Nov 2020 14:01:58 |
| User closed query 'Per CRIO source, Start Date is UNUNK2018. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).             | (b) (4), (b) (6)     | 19 Nov 2020 14:01:52 |
| Query 'Per CRIO source, Start Date is UNUNK2018. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:43:01 |
| User entered 'UN UNK 2018' reason for change: Data Entry Error                                                                                    | (b) (4)              | 18 Nov 2020 21:42:51 |
| User opened query 'Per CRIO source, Start Date is UNUNK2018. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).             | (b) (4), (b) (6)     | 18 Nov 2020 16:43:53 |
| User entered empty.                                                                                                                               | (b) (4), (b) (6)     | 06 Oct 2020 16:36:17 |



US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:35

Start date completely unknown

| Audit                                                                                                                             | User                 | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                               | (b) (4), (b) (6)     | 19 Nov 2020 14:02:01 |
| User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System). | System               | 18 Nov 2020 21:43:08 |
| DataPoint Un-verified.                                                                                                            | Krishna Shah (b) (4) | 18 Nov 2020 21:43:08 |
| User entered '0' reason for change: Data Entry Error                                                                              | (b) (4)              |                      |
|                                                                                                                                   | Krishna Shah (b) (4) | 18 Nov 2020 21:43:08 |
| User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System). | (b) (4)              |                      |
|                                                                                                                                   | System               | 18 Nov 2020 21:42:51 |
| DataPoint Verified.                                                                                                               | (b) (4), (b) (6)     | 18 Nov 2020 16:43:57 |
| User entered '1'                                                                                                                  | (b) (4), (b) (6)     | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:44:00 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:44:02 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:44:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:36:17 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:36:17 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                 | User                            | Time (GMT)                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 18 Nov 2020 21:44:49                         |
| 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) | 18 Nov 2020 21:44:49                         |
| Data point term sent to Coder Coding entries removed.                                                                                                                                                                                                                 | System<br>Krishna Shah (b) (4)  | 18 Nov 2020 21:44:14<br>18 Nov 2020 21:43:32 |
| DataPoint Verified.                                                                                                                                                                                                                                                   | (b) (4)<br>(b) (4), (b) (6)     | 18 Nov 2020 16:44:19                         |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:38:18                         |
| 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 Oct 2020 16:38:18                         |
| Data point term sent to Coder User entered 'Omeprazole'                                                                                                                                                                                                               | System<br>(b) (4), (b) (6)      | 06 Oct 2020 16:37:24<br>06 Oct 2020 16:37:15 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:44:21 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:55:35

[Indication](#)

| Audit                                                                                                                                        | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per CRIO source, Indication is GERD. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).             | (b) (4), (b) (6)     | 19 Nov 2020 14:02:27 |
| DataPoint Verified.                                                                                                                          | (b) (4), (b) (6)     | 19 Nov 2020 14:02:22 |
| Query 'Per CRIO source, Indication is GERD. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:43:39 |
| User entered 'GASTROESOPHAGEAL REFLUX DISEASE' reason for change: Data Entry Error                                                           | (b) (4)              | 18 Nov 2020 21:43:32 |
| User opened query 'Per CRIO source, Indication is GERD. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).             | (b) (4), (b) (6)     | 18 Nov 2020 16:44:53 |
| User entered 'UNK'                                                                                                                           | (b) (4), (b) (6)     | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:44:57 |
| User entered '40'   | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:44:59 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:45:02 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:45:05 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:45:09 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:45:11 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:45:13 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:45:15 |
| User entered 'un UNK 2012' | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:45:18 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:45:20 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:45:22 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:45:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:37:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:37:15 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Oct 2020 16:37:15 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                       | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 18 Nov 2020 21:45:49 |
| 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) | 18 Nov 2020 21:45:49 |
| Data point term sent to Coder                                                                                                                                                                                                                                                               | System                          | 18 Nov 2020 21:45:15 |
| Coding entries removed.                                                                                                                                                                                                                                                                     | Krishna Shah (b) (4)<br>(b) (4) | 18 Nov 2020 21:45:05 |
| DataPoint Verified.                                                                                                                                                                                                                                                                         | (b) (4), (b) (6)                | 18 Nov 2020 16:45:45 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:39:23 |
| 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 Oct 2020 16:39:23 |
| Data point term sent to Coder                                                                                                                                                                                                                                                               | System                          | 06 Oct 2020 16:38:24 |
| User entered 'Aspirin'                                                                                                                                                                                                                                                                      | (b) (4), (b) (6)                | 06 Oct 2020 16:37:40 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:35

[Prophylaxis](#)

| Audit                                                                                                                                               | User                 | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).                   | (b) (4), (b) (6)     | 19 Nov 2020 14:03:54 |
| DataPoint Verified.                                                                                                                                 | (b) (4), (b) (6)     | 19 Nov 2020 14:03:46 |
| Query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' answered with 'CRIO updated ' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:44:59 |
| User opened query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).                   | (b) (4), (b) (6)     | 18 Nov 2020 16:46:06 |
| User entered 'Yes (Y)'                                                                                                                              | (b) (4), (b) (6)     | 06 Oct 2020 16:37:40 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:55:35

[Indication](#)

| Audit                                            | User                 | Time (GMT)           |
|--------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6)     | 19 Nov 2020 14:03:57 |
| DataPoint Un-verified.                           | Krishna Shah (b) (4) | 18 Nov 2020 21:45:05 |
| User entered 'Cardiac health' reason for change: | (b) (4)              |                      |
| Data Entry Error                                 | Krishna Shah (b) (4) | 18 Nov 2020 21:45:05 |
| DataPoint Verified.                              | (b) (4)              |                      |
|                                                  | (b) (4), (b) (6)     | 18 Nov 2020 16:46:11 |
| User entered 'Supplement'                        | (b) (4), (b) (6)     | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:46:13 |
| User entered '81'   | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:46:15 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:46:17 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:46:24 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:46:25 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:46:22 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:46:30 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:46:28 |
| User entered 'un UNK 2011' | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:46:34 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:46:37 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:46:39 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:46:41 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:37:40 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:37:40 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Oct 2020 16:37:40 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                     | User                            | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                       | (b) (4), (b) (6)                | 18 Nov 2020 16:47:00 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:39:23 |
| 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 Oct 2020 16:39:23 |
| Data point term sent to Coder                                                                                                                                                                                                                             | System                          | 06 Oct 2020 16:38:26 |
| User entered 'Vitamin D3'                                                                                                                                                                                                                                 | (b) (4), (b) (6)                | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:47:02 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 18 Nov 2020 16:47:05 |
| User entered 'Supplement' | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:47:08 |
| User entered '1000' | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:47:10 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:47:11 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:47:15 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:47:17 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:47:23 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:47:26 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:47:31 |
| User entered 'un UNK 2010' | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:47:45 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:47:50 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:47:52 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:47:54 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:38:15 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Oct 2020 16:38:15 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                       | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                         | (b) (4), (b) (6)                | 18 Nov 2020 16:48:07 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:40:25 |
| 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) | 06 Oct 2020 16:40:25 |
| Data point term sent to Coder                                                                                                                                                                                                               | System                          | 06 Oct 2020 16:39:27 |
| User entered 'Women's Multi Vitamin'                                                                                                                                                                                                        | (b) (4), (b) (6)                | 06 Oct 2020 16:38:46 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:55:35

[Prophylaxis](#)

| Audit                                                                                                                                               | User                 | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).                   | (b) (4), (b) (6)     | 19 Nov 2020 14:04:34 |
| DataPoint Verified.                                                                                                                                 | (b) (4), (b) (6)     | 19 Nov 2020 14:04:31 |
| Query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' answered with 'CRIO updated ' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:47:24 |
| User opened query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).                   | (b) (4), (b) (6)     | 18 Nov 2020 16:48:21 |
| User entered 'Yes (Y)'                                                                                                                              | (b) (4), (b) (6)     | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 18 Nov 2020 16:48:26 |
| User entered 'Supplement' | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:48:28 |
| User entered '1'    | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:48:31 |
| User entered 'tablet (TABLET)' | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:48:39 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:48:41 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:48:47 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:48:44 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:48:51 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:48:53 |
| User entered 'un UNK 2010' | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:48:55 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:48:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:48:59 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:49:01 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:38:46 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Oct 2020 16:38:46 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                      | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                        | (b) (4), (b) (6)                | 18 Nov 2020 16:49:22 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:40:25 |
| 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) | 06 Oct 2020 16:40:25 |
| Data point term sent to Coder                                                                                                                                              | System                          | 06 Oct 2020 16:39:27 |
| User entered 'calcium'                                                                                                                                                     | (b) (4), (b) (6)                | 06 Oct 2020 16:39:06 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:49:24 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 18 Nov 2020 16:49:26 |
| User entered 'Supplement' | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:49:29 |
| User entered '600'  | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:49:31 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:49:33 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:49:34 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:49:37 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:49:40 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:49:43 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:49:45 |
| User entered 'un UNK 2010' | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:49:47 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:49:49 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:49:51 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:49:53 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:39:06 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:39:06 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Oct 2020 16:39:06 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                        | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)                | 18 Nov 2020 16:50:10 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:41:16 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                                    | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:41:16 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                | System                          | 06 Oct 2020 16:40:27 |
| User entered 'Probiotic'                                                                                                                                                                                                                                                                     | (b) (4), (b) (6)                | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:50:17 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 18 Nov 2020 16:50:20 |
| User entered 'Supplement' | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:50:23 |
| User entered '1'    | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:50:27 |
| User entered 'tablet (TABLET)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:50:28 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:50:30 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:50:34 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:50:36 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:50:38 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:55:35

Start date (dd MMM yyyy)

| Audit                                                                                                                                                    | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per CRIO source, Start Date is 2018. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).                         | (b) (4), (b) (6)     | 19 Nov 2020 14:05:06 |
| DataPoint Verified.                                                                                                                                      | (b) (4), (b) (6)     | 19 Nov 2020 14:05:01 |
| Query 'Per CRIO source, Start Date is 2018. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated per source.' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:51:03 |
| User entered 'UN UNK 2018' reason for change: Data Entry Error                                                                                           | Krishna Shah (b) (4) | 18 Nov 2020 21:50:56 |
| User opened query 'Per CRIO source, Start Date is 2018. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).                         | (b) (4), (b) (6)     | 18 Nov 2020 16:51:02 |
| User entered 'un UNK 2008'                                                                                                                               | (b) (4), (b) (6)     | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:51:07 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:51:10 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:51:12 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:51:14 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:39:30 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:39:30 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Oct 2020 16:39:30 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                         | User                            | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                           | (b) (4), (b) (6)                | 18 Nov 2020 16:51:35 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:41:15 |
| 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 Oct 2020 16:41:15 |
| Data point term sent to Coder                                                                                                                                                                                                                 | System                          | 06 Oct 2020 16:40:29 |
| User entered 'Shingrix'                                                                                                                                                                                                                       | (b) (4), (b) (6)                | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:51:37 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:51:40 |
| User entered 'Vaccine' | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:51:43 |
| User entered 'UNK'  | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:51:47 |
| User entered 'mL (mL)' | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:51:50 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:51:56 |
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:51:58 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                                        | User             | Time (GMT)           |
|----------------------------------------------|------------------|----------------------|
| DataPoint Verified.                          | (b) (4), (b) (6) | 18 Nov 2020 16:52:00 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:52:04 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:52:06 |
| User entered '21 Feb 2019' | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:52:07 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:52:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:52:12 |
| User entered '21 Feb 2019' | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:52:14 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:40:04 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:40:04 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                            | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY ELLIPTA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Nov 2020 21:52:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                                                                                                                        | Coder Import (b) (4) | 18 Nov 2020 21:52:48 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                                                    | System               | 18 Nov 2020 21:52:23 |
| Coding entries removed.                                                                                                                                                                                                                                                                                                                                                          | Krishna Shah (b) (4) | 18 Nov 2020 21:51:47 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)     | 18 Nov 2020 16:52:38 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY ELLIPTA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Oct 2020 16:42:21 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                                                                                                                        | Coder Import (b) (4) | 06 Oct 2020 16:42:21 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                                                    | System               | 06 Oct 2020 16:41:30 |
| User entered 'Trelegy Ellipta'                                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)     | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:52:41 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:55:35

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                 | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per CRIO source, Indication is "Asthma". Please reconcile and update CRIO or EDC as applicable. Please also note, per Medical History this is reported as COPD and not Asthma. Please reconcile and update if applicable.' (Site from CRA). DataPoint Verified.    | (b) (4), (b) (6)     | 19 Nov 2020 14:06:23 |
|                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)     | 19 Nov 2020 14:06:19 |
| Query 'Per CRIO source, Indication is "Asthma". Please reconcile and update CRIO or EDC as applicable. Please also note, per Medical History this is reported as COPD and not Asthma. Please reconcile and update if applicable.' answered with 'updated per source' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:51:54 |
|                                                                                                                                                                                                                                                                                       | (b) (4)              |                      |
| User entered 'Asthma' reason for change: Data Entry Error                                                                                                                                                                                                                             | Krishna Shah (b) (4) | 18 Nov 2020 21:51:47 |
|                                                                                                                                                                                                                                                                                       | (b) (4)              |                      |
| User opened query 'Per CRIO source, Indication is "Asthma". Please reconcile and update CRIO or EDC as applicable. Please also note, per Medical History this is reported as COPD and not Asthma. Please reconcile and update if applicable.' (Site from CRA).                        | (b) (4), (b) (6)     | 18 Nov 2020 16:55:28 |
|                                                                                                                                                                                                                                                                                       |                      |                      |
| User entered 'COPD'                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)     | 06 Oct 2020 16:40:38 |
|                                                                                                                                                                                                                                                                                       |                      |                      |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:55:50 |
| User entered '100'  | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:55:52 |
| User entered 'ug (ug)' | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:55:55 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:55:57 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:55:59 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                                                                 | User             | Time (GMT)           |
|-----------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6) | 18 Nov 2020 16:56:02 |
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:56:04 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:56:06 |
| User entered 'un UNK 2018' | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:56:11 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:56:13 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:56:16 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:56:18 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Oct 2020 16:40:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Oct 2020 16:40:38 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                      | User                            | Time (GMT)                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                        | (b) (4), (b) (6)                | 18 Nov 2020 16:56:39                         |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:42:21                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                  | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:42:21                         |
| Data point term sent to Coder User entered 'Albuterol'                                                                                                                                                                                                                     | System<br>(b) (4), (b) (6)      | 06 Oct 2020 16:41:31<br>06 Oct 2020 16:41:14 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:56:41 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:56:43 |
| User entered 'COPD' | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:56:46 |
| User entered '90'   | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:56:48 |
| User entered 'ug (ug)' | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:56:50 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:56:54 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:56:56 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                                                                 | User             | Time (GMT)           |
|-----------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6) | 18 Nov 2020 16:56:58 |
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:57:01 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:57:03 |
| User entered 'un UNK 2018' | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:57:05 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:57:06 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:57:08 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:57:10 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:41:14 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:41:14 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:41:14 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                                         | User                            | Time (GMT)                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                           | (b) (4), (b) (6)                | 18 Nov 2020 16:57:34                         |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM;SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL;IPRATROPIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 09 Oct 2020 10:56:23                         |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                                                                                                                                                          | Coder Import (b) (4)<br>(b) (4) | 09 Oct 2020 10:56:23                         |
| Data point term sent to Coder User entered 'Ipratropium-albuterol'                                                                                                                                                                                                                                                                            | System<br>(b) (4), (b) (6)      | 06 Oct 2020 16:42:31<br>06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:57:36 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:57:38 |
| User entered 'COPD' | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:57:40 |
| User entered '3'    | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:55:35

[Dose unit](#)

| Audit                                                                                                                                                 | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per CRIO source, Dose unit is mg. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).<br>DataPoint Verified.  | (b) (4), (b) (6)     | 19 Nov 2020 14:06:50 |
|                                                                                                                                                       | (b) (4), (b) (6)     | 19 Nov 2020 14:06:40 |
| Query 'Per CRIO source, Dose unit is mg. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated per source ' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:52:23 |
| User entered 'mg (mg)' reason for change: Data Entry Error                                                                                            | (b) (4)              | 18 Nov 2020 21:52:15 |
| User opened query 'Per CRIO source, Dose unit is mg. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).                         | (b) (4), (b) (6)     | 18 Nov 2020 16:58:04 |
| User entered 'mL (mL)'                                                                                                                                | (b) (4), (b) (6)     | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:58:07 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 18 Nov 2020 16:58:09 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:58:11 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                                                                 | User             | Time (GMT)           |
|-----------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6) | 18 Nov 2020 16:58:13 |
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:58:16 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:58:18 |
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:58:20 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:58:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:58:26 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:58:30 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:41:48 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:41:48 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:41:48 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                     | User                            | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                       | (b) (4), (b) (6)                | 18 Nov 2020 16:58:51 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:44:19 |
| 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 Oct 2020 16:44:19 |
| Data point term sent to Coder                                                                                                                                                                                                             | System                          | 06 Oct 2020 16:43:33 |
| User entered 'Budesonide'                                                                                                                                                                                                                 | (b) (4), (b) (6)                | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:58:54 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:58:56 |
| User entered 'COPD' | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:58:58 |
| User entered '2'    | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:59:00 |
| User entered 'mL (mL)' | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:59:05 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:55:35

[Frequency](#)

| Audit                                                                                                                                      | User                 | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per CRIO source, frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).             | (b) (4), (b) (6)     | 19 Nov 2020 14:07:28 |
| DataPoint Verified.                                                                                                                        | (b) (4), (b) (6)     | 19 Nov 2020 14:07:21 |
| Query 'Per CRIO source, frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated' (Site from CRA). | Krishna Shah (b) (4) | 18 Nov 2020 21:50:17 |
| User entered 'as needed (PRN)' reason for change: Data Entry Error                                                                         | (b) (4)              | 18 Nov 2020 21:50:06 |
| User opened query 'Per CRIO source, frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).             | (b) (4), (b) (6)     | 18 Nov 2020 16:59:29 |
| User entered 'twice daily (BID)'                                                                                                           | (b) (4), (b) (6)     | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:59:34 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                                                                 | User             | Time (GMT)           |
|-----------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6) | 18 Nov 2020 16:59:37 |
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:59:39 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 18 Nov 2020 16:59:41 |
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:59:43 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 18 Nov 2020 16:59:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 16:59:46 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 18 Nov 2020 16:59:48 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 21:50:06 |
| User entered '2'    | System | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Nov 2020 21:50:06 |
| User entered '1'    | System | 06 Oct 2020 16:42:42 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered empty.      | System | 18 Nov 2020 21:50:06 |
| User entered '804 (804)' | System | 06 Oct 2020 16:42:42 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                              | User                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Please add source in CRIO for TDAP, Influenza, and Pneumococcal' (Site from CRA).                                                                                                                               | (b) (4), (b) (6)     | 19 Nov 2020 14:11:10 |
| DataPoint Verified.                                                                                                                                                                                                                | (b) (4), (b) (6)     | 19 Nov 2020 14:11:04 |
| Query 'Please add source in CRIO for TDAP, Influenza, and Pneumococcal' answered with 'Please see scanned med hx under patient header for source of all vaccines. ' (Site from CRA).                                               | Krishna Shah (b) (4) | 18 Nov 2020 21:46:37 |
| User opened query 'Please add source in CRIO for TDAP, Influenza, and Pneumococcal' (Site from CRA).                                                                                                                               | (b) (4), (b) (6)     | 18 Nov 2020 17:04:09 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Oct 2020 16:44:20 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                          | Coder Import (b) (4) | 06 Oct 2020 16:44:20 |
| Data point term sent to Coder                                                                                                                                                                                                      | System               | 06 Oct 2020 16:43:36 |
| User entered 'Diphtheria, tetanus, pertussis'                                                                                                                                                                                      | (b) (4), (b) (6)     | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 19 Nov 2020 14:11:14 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 19 Nov 2020 14:11:57 |
| User entered 'Vaccine' | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:11:37 |
| User entered 'UNK'  | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 19 Nov 2020 14:12:01 |
| User entered 'mL (mL)' | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:12:07 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 14:12:04 |
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:12:10 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                                        | User             | Time (GMT)           |
|----------------------------------------------|------------------|----------------------|
| DataPoint Verified.                          | (b) (4), (b) (6) | 19 Nov 2020 14:12:13 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:12:20 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 14:12:24 |
| User entered '01 May 2012' | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:12:29 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 19 Nov 2020 14:12:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 19 Nov 2020 14:12:42 |
| User entered '1 May 2012' | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 19 Nov 2020 14:12:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:43:31 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:43:31 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                                  | User                            | Time (GMT)                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|
| DataPoint Verified.                                                                                                                                                                                                    | (b) (4), (b) (6)                | 19 Nov 2020 14:13:05                         |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.                            | Coder Import (b) (4)<br>(b) (4) | 01 Nov 2020 21:23:02                         |
| 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) | 01 Nov 2020 21:23:02                         |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Oct 2020 16:45:24                         |
| 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 Oct 2020 16:45:24                         |
| Data point term sent to Coder User entered 'Influenza'                                                                                                                                                                 | System<br>(b) (4), (b) (6)      | 06 Oct 2020 16:44:36<br>06 Oct 2020 16:44:16 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 19 Nov 2020 14:13:10 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 19 Nov 2020 14:13:22 |
| User entered 'Vaccine' | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:13:27 |
| User entered 'UNK'  | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 19 Nov 2020 14:13:31 |
| User entered 'mL (mL)' | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:13:35 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 19 Nov 2020 14:13:39 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:13:42 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                                        | User             | Time (GMT)           |
|----------------------------------------------|------------------|----------------------|
| DataPoint Verified.                          | (b) (4), (b) (6) | 19 Nov 2020 14:13:50 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:13:54 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 14:14:00 |
| User entered '20 Oct 2018' | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:14:04 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 19 Nov 2020 14:14:13 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 14:14:17 |
| User entered '20 Oct 2018' | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 19 Nov 2020 14:14:27 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:44:16 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:44:16 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:44:16 |

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:55:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                 | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                   | (b) (4), (b) (6)     | 19 Nov 2020 14:14:43 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Oct 2020 16:46:30 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                             | Coder Import (b) (4) | 06 Oct 2020 16:46:30 |
| Data point term sent to Coder                                                                                                                                                                         | System               | 06 Oct 2020 16:45:41 |
| User entered 'Pneumococcal'                                                                                                                                                                           | (b) (4), (b) (6)     | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Prophylaxis](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 19 Nov 2020 14:14:54 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 19 Nov 2020 14:14:59 |
| User entered 'Vaccine' | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:15:04 |
| User entered 'UNK'  | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 19 Nov 2020 14:15:13 |
| User entered 'mL (mL)' | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:15:17 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Frequency](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 14:15:21 |
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:15:24 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Route of administration](#)

| Audit                                        | User             | Time (GMT)           |
|----------------------------------------------|------------------|----------------------|
| DataPoint Verified.                          | (b) (4), (b) (6) | 19 Nov 2020 14:15:27 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:15:32 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 19 Nov 2020 14:15:36 |
| User entered '09 Feb 2016' | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 14:15:40 |
| User entered '0'    | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 19 Nov 2020 14:15:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 19 Nov 2020 14:16:05 |
| User entered '9 Feb 2016' | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 19 Nov 2020 14:16:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 06 Oct 2020 16:45:38 |



US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 09:55:35**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 16:45:38 |

US3822043

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:55:35**

[Were any concomitant procedures performed?](#)

| Audit                                                      | User                  | Time (GMT)           |
|------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6)      | 04 Nov 2020 20:48:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Kelly Woodell (b) (4) | 23 Oct 2020 17:42:51 |
| User entered 'No (N)'                                      | Krishna Shah (b) (4)  | 06 Oct 2020 20:29:45 |

US3822043

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 04 Nov 2020 20:48:24 |
| User entered '05 Sep 2020' | Kelly Woodell (b) (4) | 23 Oct 2020 17:43:24 |
|                            | (b) (4)               |                      |

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:55:35

[Procedure/Surgery](#)

| Audit                                                                                                                                                                                                                                                                           | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                             | (b) (4), (b) (6)                 | 23 Nov 2020 20:54:24 |
| Query 'Please contact subject as soon as possible instead of waiting until next scheduled phone call. Due to the subject having an SAE, we need as much information as possible.' answered with 'UPDATED' (Site from CRA).                                                      | (b) (4), (b) (6)                 | 23 Nov 2020 14:07:26 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                          | (b) (4), (b) (6)                 | 23 Nov 2020 14:07:21 |
| User entered 'CT CHEST FOR LUNG CANCER SCREENING - Moderate centrilobular emphysema, Moderate-severe coronary arterial calcifications. Normal heart size.' reason for change: Data Entry Error                                                                                  | (b) (4), (b) (6)                 | 23 Nov 2020 14:07:21 |
| User opened query 'Please contact subject as soon as possible instead of waiting until next scheduled phone call. Due to the subject having an SAE, we need as much information as possible.' (Site from CRA).                                                                  | (b) (4), (b) (6)                 | 19 Nov 2020 14:18:26 |
| User closed query 'Per Hem/Onc note on 21OCT2020 visit, subject was to have additional CT imaging. Has this been completed? if so, kindly obtain records and update EDC. Thank you.' (Site from CRA).                                                                           | (b) (4), (b) (6)                 | 19 Nov 2020 14:18:26 |
| Query 'Per Hem/Onc note on 21OCT2020 visit, subject was to have additional CT imaging. Has this been completed? if so, kindly obtain records and update EDC. Thank you.' answered with 'Will confirm with patient at next phone call and update if completed.' (Site from CRA). | Krishna Shah (b) (4)<br>(b) (4)  | 18 Nov 2020 21:55:15 |
| User opened query 'Per Hem/Onc note on 21OCT2020 visit, subject was to have additional CT imaging. Has this been completed? if so, kindly obtain records and update EDC. Thank you.' (Site from CRA).                                                                           | (b) (4), (b) (6)                 | 04 Nov 2020 20:51:53 |
| DataPoint Verified.                                                                                                                                                                                                                                                             | (b) (4), (b) (6)                 | 04 Nov 2020 20:48:24 |
| User entered 'CT Chest'                                                                                                                                                                                                                                                         | Kelly Woodell (b) (4)<br>(b) (4) | 23 Oct 2020 17:43:24 |

US3822043

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                               | User                  | Time (GMT)           |
|-------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                 | (b) (4), (b) (6)      | 04 Nov 2020 20:48:24 |
| User entered 'Medical History (MH)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:43:24 |

US3822043

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:55:35**

[If indication is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 04 Nov 2020 20:48:24 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:43:24 |



US3822043

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 04 Nov 2020 20:48:24 |
| User entered '02 Oct 2020' | Kelly Woodell (b) (4) | 23 Oct 2020 17:43:59 |
|                            | (b) (4)               |                      |

US3822043

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Procedure/Surgery](#)

| Audit                                         | User                  | Time (GMT)           |
|-----------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                           | (b) (4), (b) (6)      | 04 Nov 2020 20:48:24 |
| User entered 'Ultrasounds guided core biopsy' | Kelly Woodell (b) (4) | 23 Oct 2020 17:43:59 |

US3822043

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Indication](#)

| Audit                             | User                  | Time (GMT)           |
|-----------------------------------|-----------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)      | 04 Nov 2020 20:48:24 |
| User entered 'Adverse Event (AE)' | Kelly Woodell (b) (4) | 23 Oct 2020 17:43:59 |

US3822043

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 09:55:35**

[If indication is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 04 Nov 2020 20:48:24 |
| User entered empty. | Kelly Woodell (b) (4) | 23 Oct 2020 17:43:59 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered<br>'USA-US126-2020-MRNA-1273-P301000006' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Yes (Y)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |



**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Yes (Y)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Investigator's First Name](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.     | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Christina' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Kennelly' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [Street](#)

| Audit                                                                                                               | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                 | (b) (4), (b) (6)      | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.                                                                                                | (b) (4), (b) (6)      | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety.                                                                                             | System                | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.                                                                                              | System                | 19 Nov 2020 14:28:16 |
| User entered empty.                                                                                                 | System                | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.                                                                                                | (b) (4), (b) (6)      | 19 Nov 2020 14:28:02 |
| DataPoint Verified.                                                                                                 | (b) (4), (b) (6)      | 10 Nov 2020 19:55:02 |
| User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).             | (b) (4), (b) (6)      | 10 Nov 2020 19:54:57 |
| Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA). | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:26 |
| User entered '6060 Piedmont Row Drive South'                                                                        | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:21 |
| User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).             | (b) (4), (b) (6)      | 04 Nov 2020 19:03:36 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [City](#)

| Audit                    | User                  | Time (GMT)           |
|--------------------------|-----------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)      | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.     | (b) (4), (b) (6)      | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety.  | System                | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.   | System                | 19 Nov 2020 14:28:16 |
| User entered empty.      | System                | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.     | (b) (4), (b) (6)      | 19 Nov 2020 14:28:02 |
| DataPoint Verified.      | (b) (4), (b) (6)      | 10 Nov 2020 19:55:02 |
| User entered 'Charlotte' | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:21 |



US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Site Address: State](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety. | System                           | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.  | System                           | 19 Nov 2020 14:28:16 |
| User entered empty.     | System                           | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 19 Nov 2020 14:28:02 |
| DataPoint Verified.     | (b) (4), (b) (6)                 | 10 Nov 2020 19:55:02 |
| User entered 'NC'       | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 17:12:21 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Site Address: Postal Code](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety. | System                           | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.  | System                           | 19 Nov 2020 14:28:16 |
| User entered empty.     | System                           | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 19 Nov 2020 14:28:02 |
| DataPoint Verified.     | (b) (4), (b) (6)                 | 10 Nov 2020 19:55:02 |
| User entered '28210'    | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 17:12:21 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 13:46:34 |
| User entered 'US'    | System           | 26 Oct 2020 21:07:42 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 24 Nov 2020 19:28:52 |
| User entered '3' | System | 19 Nov 2020 14:28:16 |
| User entered '2' | System | 28 Oct 2020 13:46:45 |
| User entered '1' | System | 26 Oct 2020 21:07:42 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered<br>'USA-US126-2020-MRNA-1273-P301000006' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Yes (Y)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |



**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Yes (Y)' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Investigator's First Name](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.     | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Christina' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Kennelly' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [Street](#)

| Audit                                                                                                               | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                 | (b) (4), (b) (6)      | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.                                                                                                | (b) (4), (b) (6)      | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety.                                                                                             | System                | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.                                                                                              | System                | 19 Nov 2020 14:28:16 |
| User entered empty.                                                                                                 | System                | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.                                                                                                | (b) (4), (b) (6)      | 19 Nov 2020 14:28:02 |
| DataPoint Verified.                                                                                                 | (b) (4), (b) (6)      | 10 Nov 2020 19:55:02 |
| User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).             | (b) (4), (b) (6)      | 10 Nov 2020 19:54:57 |
| Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA). | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:26 |
| User entered '6060 Piedmont Row Drive South'                                                                        | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:21 |
| User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).             | (b) (4), (b) (6)      | 04 Nov 2020 19:03:36 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [City](#)

| Audit                    | User                  | Time (GMT)           |
|--------------------------|-----------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)      | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.     | (b) (4), (b) (6)      | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety.  | System                | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.   | System                | 19 Nov 2020 14:28:16 |
| User entered empty.      | System                | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.     | (b) (4), (b) (6)      | 19 Nov 2020 14:28:02 |
| DataPoint Verified.      | (b) (4), (b) (6)      | 10 Nov 2020 19:55:02 |
| User entered 'Charlotte' | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:21 |



US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [State](#)

| Audit                   | User                  | Time (GMT)           |
|-------------------------|-----------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)      | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.    | (b) (4), (b) (6)      | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety. | System                | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.  | System                | 19 Nov 2020 14:28:16 |
| User entered empty.     | System                | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.    | (b) (4), (b) (6)      | 19 Nov 2020 14:28:02 |
| DataPoint Verified.     | (b) (4), (b) (6)      | 10 Nov 2020 19:55:02 |
| User entered 'NC'       | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:21 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Site Address: Postal Code](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety. | System                           | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.  | System                           | 19 Nov 2020 14:28:16 |
| User entered empty.     | System                           | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 19 Nov 2020 14:28:02 |
| DataPoint Verified.     | (b) (4), (b) (6)                 | 10 Nov 2020 19:55:02 |
| User entered '28210'    | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 17:12:21 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 13:46:34 |
| User entered 'US'    | System           | 26 Oct 2020 21:07:42 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 24 Nov 2020 19:28:52 |
| User entered '3' | System | 19 Nov 2020 14:28:16 |
| User entered '2' | System | 28 Oct 2020 13:46:45 |
| User entered '1' | System | 26 Oct 2020 21:07:42 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 09:55:35**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| User entered '26/Oct/2020 21:07' | System           | 26 Oct 2020 21:07:42 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:55:35

**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 Nov 2020 20:43:11 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 13:46:34 |
| User entered '1'     | (b) (4), (b) (6) | 26 Oct 2020 21:07:42 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered<br>'USA-US126-2020-MRNA-1273-P301000006' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Serious](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Yes (Y)' | System           | 26 Oct 2020 20:56:27 |



**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Yes (Y)' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Investigator's First Name](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.     | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Christina' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Kennelly' | System           | 26 Oct 2020 20:56:27 |



US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [Street](#)

| Audit                                                                                                               | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                 | (b) (4), (b) (6)      | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.                                                                                                | (b) (4), (b) (6)      | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety.                                                                                             | System                | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.                                                                                              | System                | 19 Nov 2020 14:28:16 |
| User entered empty.                                                                                                 | System                | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.                                                                                                | (b) (4), (b) (6)      | 19 Nov 2020 14:28:02 |
| DataPoint Verified.                                                                                                 | (b) (4), (b) (6)      | 10 Nov 2020 19:55:02 |
| User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).             | (b) (4), (b) (6)      | 10 Nov 2020 19:54:57 |
| Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA). | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:26 |
| User entered '6060 Piedmont Row Drive South'                                                                        | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:21 |
| User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).             | (b) (4), (b) (6)      | 04 Nov 2020 19:03:36 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [City](#)

| Audit                    | User                             | Time (GMT)           |
|--------------------------|----------------------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.     | (b) (4), (b) (6)                 | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety.  | System                           | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.   | System                           | 19 Nov 2020 14:28:16 |
| User entered empty.      | System                           | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.     | (b) (4), (b) (6)                 | 19 Nov 2020 14:28:02 |
| DataPoint Verified.      | (b) (4), (b) (6)                 | 10 Nov 2020 19:55:02 |
| User entered 'Charlotte' | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 17:12:21 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: State

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety. | System                           | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.  | System                           | 19 Nov 2020 14:28:16 |
| User entered empty.     | System                           | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 19 Nov 2020 14:28:02 |
| DataPoint Verified.     | (b) (4), (b) (6)                 | 10 Nov 2020 19:55:02 |
| User entered 'NC'       | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 17:12:21 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Site Address: Postal Code](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety. | System                           | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.  | System                           | 19 Nov 2020 14:28:16 |
| User entered empty.     | System                           | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 19 Nov 2020 14:28:02 |
| DataPoint Verified.     | (b) (4), (b) (6)                 | 10 Nov 2020 19:55:02 |
| User entered '28210'    | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 17:12:21 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 13:46:34 |
| User entered 'US'    | System           | 26 Oct 2020 21:07:42 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 24 Nov 2020 19:28:52 |
| User entered '3' | System | 19 Nov 2020 14:28:16 |
| User entered '2' | System | 28 Oct 2020 13:46:45 |
| User entered '1' | System | 26 Oct 2020 21:07:42 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 09:55:35**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| User entered '28/Oct/2020 13:46' | System           | 28 Oct 2020 13:46:45 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:55:35

**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) | 19 Nov 2020 14:28:02 |
| DataPoint Verified.  | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| User entered '1'     | (b) (4), (b) (6) | 28 Oct 2020 13:46:45 |



**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered<br>'USA-US126-2020-MRNA-1273-P301000006' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Yes (Y)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Yes (Y)' | System           | 26 Oct 2020 20:56:27 |



**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Investigator's First Name](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.     | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Christina' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Kennelly' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [Street](#)

| Audit                                                                                                               | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                 | (b) (4), (b) (6)      | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.                                                                                                | (b) (4), (b) (6)      | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety.                                                                                             | System                | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.                                                                                              | System                | 19 Nov 2020 14:28:16 |
| User entered empty.                                                                                                 | System                | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.                                                                                                | (b) (4), (b) (6)      | 19 Nov 2020 14:28:02 |
| DataPoint Verified.                                                                                                 | (b) (4), (b) (6)      | 10 Nov 2020 19:55:02 |
| User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).             | (b) (4), (b) (6)      | 10 Nov 2020 19:54:57 |
| Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA). | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:26 |
| User entered '6060 Piedmont Row Drive South'                                                                        | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:21 |
| User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).             | (b) (4), (b) (6)      | 04 Nov 2020 19:03:36 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [City](#)

| Audit                    | User                             | Time (GMT)           |
|--------------------------|----------------------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.     | (b) (4), (b) (6)                 | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety.  | System                           | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.   | System                           | 19 Nov 2020 14:28:16 |
| User entered empty.      | System                           | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.     | (b) (4), (b) (6)                 | 19 Nov 2020 14:28:02 |
| DataPoint Verified.      | (b) (4), (b) (6)                 | 10 Nov 2020 19:55:02 |
| User entered 'Charlotte' | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 17:12:21 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: State

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety. | System                           | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.  | System                           | 19 Nov 2020 14:28:16 |
| User entered empty.     | System                           | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 19 Nov 2020 14:28:02 |
| DataPoint Verified.     | (b) (4), (b) (6)                 | 10 Nov 2020 19:55:02 |
| User entered 'NC'       | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 17:12:21 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Site Address: Postal Code](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety. | System                           | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.  | System                           | 19 Nov 2020 14:28:16 |
| User entered empty.     | System                           | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 19 Nov 2020 14:28:02 |
| DataPoint Verified.     | (b) (4), (b) (6)                 | 10 Nov 2020 19:55:02 |
| User entered '28210'    | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 17:12:21 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 13:46:34 |
| User entered 'US'    | System           | 26 Oct 2020 21:07:42 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 24 Nov 2020 19:28:52 |
| User entered '3' | System | 19 Nov 2020 14:28:16 |
| User entered '2' | System | 28 Oct 2020 13:46:45 |
| User entered '1' | System | 26 Oct 2020 21:07:42 |



**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 09:55:35**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 24 Nov 2020 21:50:48 |
| User entered '19/Nov/2020 14:28' | System           | 19 Nov 2020 14:28:16 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:55:35

**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) | 24 Nov 2020 21:50:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 19:28:40 |
| User entered '1'     | (b) (4), (b) (6) | 19 Nov 2020 14:28:16 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered<br>'USA-US126-2020-MRNA-1273-P301000006' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

**Serious**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Yes (Y)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |



**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'No (N)' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Yes (Y)' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

[Investigator's First Name](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.     | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Christina' | System           | 26 Oct 2020 20:56:27 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 26 Oct 2020 21:07:34 |
| User entered 'Kennelly' | System           | 26 Oct 2020 20:56:27 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [Street](#)

| Audit                                                                                                               | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                 | (b) (4), (b) (6)      | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.                                                                                                | (b) (4), (b) (6)      | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety.                                                                                             | System                | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.                                                                                              | System                | 19 Nov 2020 14:28:16 |
| User entered empty.                                                                                                 | System                | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.                                                                                                | (b) (4), (b) (6)      | 19 Nov 2020 14:28:02 |
| DataPoint Verified.                                                                                                 | (b) (4), (b) (6)      | 10 Nov 2020 19:55:02 |
| User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).             | (b) (4), (b) (6)      | 10 Nov 2020 19:54:57 |
| Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA). | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:26 |
| User entered '6060 Piedmont Row Drive South'                                                                        | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:21 |
| User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).             | (b) (4), (b) (6)      | 04 Nov 2020 19:03:36 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [City](#)

| Audit                    | User                  | Time (GMT)           |
|--------------------------|-----------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)      | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.     | (b) (4), (b) (6)      | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety.  | System                | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.   | System                | 19 Nov 2020 14:28:16 |
| User entered empty.      | System                | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.     | (b) (4), (b) (6)      | 19 Nov 2020 14:28:02 |
| DataPoint Verified.      | (b) (4), (b) (6)      | 10 Nov 2020 19:55:02 |
| User entered 'Charlotte' | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:21 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [State](#)

| Audit                   | User                  | Time (GMT)           |
|-------------------------|-----------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)      | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.    | (b) (4), (b) (6)      | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety. | System                | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.  | System                | 19 Nov 2020 14:28:16 |
| User entered empty.     | System                | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.    | (b) (4), (b) (6)      | 19 Nov 2020 14:28:02 |
| DataPoint Verified.     | (b) (4), (b) (6)      | 10 Nov 2020 19:55:02 |
| User entered 'NC'       | Kelly Woodell (b) (4) | 10 Nov 2020 17:12:21 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:55:35

Site Address: [Postal Code](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 24 Nov 2020 21:50:48 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 24 Nov 2020 19:28:40 |
| Un-reviewed for Safety. | System                           | 19 Nov 2020 14:28:16 |
| DataPoint Un-verified.  | System                           | 19 Nov 2020 14:28:16 |
| User entered empty.     | System                           | 19 Nov 2020 14:28:16 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 19 Nov 2020 14:28:02 |
| DataPoint Verified.     | (b) (4), (b) (6)                 | 10 Nov 2020 19:55:02 |
| User entered '28210'    | Kelly Woodell (b) (4)<br>(b) (4) | 10 Nov 2020 17:12:21 |



**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 04 Nov 2020 20:43:11 |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Oct 2020 13:46:34 |
| User entered 'US'    | System           | 26 Oct 2020 21:07:42 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:55:35**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 24 Nov 2020 19:28:52 |
| User entered '3' | System | 19 Nov 2020 14:28:16 |
| User entered '2' | System | 28 Oct 2020 13:46:45 |
| User entered '1' | System | 26 Oct 2020 21:07:42 |

**US3822043**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (4)**

**Generated On: 26 Nov 2020 09:55:35**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 24 Nov 2020 21:50:48 |
| User entered '24/Nov/2020 19:28' | System           | 24 Nov 2020 19:28:52 |

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:55:35

**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) | 24 Nov 2020 21:50:48 |
| User entered '1'    | (b) (4), (b) (6) | 24 Nov 2020 19:28:52 |