

US3342239 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:34:57

All time stamps listed in this document are displayed in GMT

US3342239

**Form: Participant Creation**

**Data signed:** (b) (4) 12 Mar 2021 23:18:14

**Generated On:** 11 Aug 2021 22:34:57

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[Participant ID](#)

US3342239

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

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US3342239

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 10 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | SCRN                                    |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1990                                                                                                                                                               |
| Age                                       | 30                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 30                                                                                                                                                                         |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>                                                                                                      |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |                                                                                                                                                                            |
| White                                     | True                                                                                                                                                                       |
| Black                                     | False                                                                                                                                                                      |
| Asian                                     | False                                                                                                                                                                      |
| American Indian or Alaska Native          | False                                                                                                                                                                      |
| Native Hawaiian or other Pacific Islander | False                                                                                                                                                                      |
| Other                                     | False                                                                                                                                                                      |
| If race is Other, specify _____           |                                                                                                                                                                            |
| Unknown                                   | False                                                                                                                                                                      |
| Not reported                              | False                                                                                                                                                                      |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Mar 2021 23:18:14

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|                                              |                                              |
|----------------------------------------------|----------------------------------------------|
| Date of Informed Consent (dd MMM yyyy)       | 10 SEP 2020                                  |
| Month and Year of Informed Consent (derived) | SEP 2020                                     |
| Year of Informed Consent (derived)           | 2020                                         |
| Protocol Version                             | Amendment 1 <input type="radio"/>            |
|                                              | Amendment 2 <input type="radio"/>            |
|                                              | Amendment 3 <input checked="" type="radio"/> |
|                                              | Amendment 4 <input type="radio"/>            |
|                                              | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?       | Yes <input checked="" type="radio"/>         |
|                                              | No <input type="radio"/>                     |
| If No, indicate reason for screen fail       | Withdrew Consent <input type="radio"/>       |
|                                              | Inclusion/Exclusion <input type="radio"/>    |
|                                              | Cohort Full <input type="radio"/>            |
|                                              | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify  |                                              |
| Was this participant screened previously?    | Yes <input type="radio"/>                    |
|                                              | No <input checked="" type="radio"/>          |
| If Yes, previous participant number          |                                              |
| Enrollment Trigger                           | 1                                            |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Mar 2021 23:18:14

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Mar 2021 23:18:14

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Mar 2021 23:18:14

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|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | BILATERAL TUBAL LIGATION                                         |
| Start date (dd MMM yyyy)                          | 02 MAR 2012                                                      |
| 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) | 02 MAR 2012                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | MAR 2012                                                         |
| Start Year (derived)                              | 2012                                                             |
| Stop Month and Year (derived)                     | MAR 2012                                                         |
| Stop Year (derived)                               | 2012                                                             |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Mar 2021 23:18:14

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|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | GALLSTONES                                                       |
| Start date (dd MMM yyyy)                                | UN MAR 2019                                                      |
| Start date completely unknown                           | False                                                            |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |                                                                  |
| Stop date completely unknown                            | False                                                            |
| Start Month and Year (derived)                          | MAR 2019                                                         |
| Start Year (derived)                                    | 2019                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | L5 DEFECTIVE DISC                                                |
| Start date (dd MMM yyyy)                                | UN MAR 2019                                                      |
| Start date completely unknown                           | False                                                            |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |                                                                  |
| Stop date completely unknown                            | False                                                            |
| Start Month and Year (derived)                          | MAR 2019                                                         |
| Start Year (derived)                                    | 2019                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Mar 2021 23:18:14

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|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | HYPERTENSION                                                     |
| Start date (dd MMM yyyy)                                | UN JUN 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)                          | JUN 2018                                                         |
| Start Year (derived)                                    | 2018                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 10 SEP 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 16:48 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 10 SEP 2020 16:48                    |
| Height ( <i>xxx.x</i> )                   | 162.5 cm                             |
| Weight ( <i>xxx.x</i> )                   | 64.2 kg                              |
| BMI ( <i>xxx.x</i> )                      | 24.31243 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|                                           | Axillary <input type="radio"/>       |
|                                           | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:18:14

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Mar 2021 23:18:14

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Date of assessment (dd MMM yyyy) 10 SEP 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (dd MMM yyyy) 02 MAR 2012

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:18:14

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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 ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:18:14

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

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 10 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT1                                  |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Mar 2021 23:18:25

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What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 113263

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/m<sup>2</sup>) Yes ☐ No ☒

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 10 SEP 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 16:48 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 10 SEP 2020 16:48                                                                                      |
| Temperature (xxx.x)                 | 98.7 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 71 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 112 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 74 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 10 SEP 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 18:17 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 10 SEP 2020 18:17                                                                                      |
| Temperature (xxx.x)                 | 98.9 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 69 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 112 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 54 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:18:15

Generated On: 11 Aug 2021 22:34:57

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 SEP 2020

What was the treatment time? (00:00-23:59) 17:46 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 17:46

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:18:15

Generated On: 11 Aug 2021 22:34:57

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 10 SEP 2020                          |
| Collection time (00:00-23:59)      | 17:18 (24 HR)                        |
| Collection date and time (derived) | 10 SEP 2020 17:18                    |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 23:18:15

Generated On: 11 Aug 2021 22:34:57

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 10 SEP 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 17:20                           | 10 SEP 2020 17:20                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:15

Generated On: 11 Aug 2021 22:34:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

10 SEP 2020 18:22

PC Open Date & Time

10 SEP 2020 18:06

PC Close Date & Time

10 SEP 2020 20:36

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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        | 11 SEP 2020 03:53 |
| PC Open Date & Time  | 10 SEP 2020 21:31 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °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):

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

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

PC Time Stamp 12 SEP 2020 04:24

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:34:57

**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):

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

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

PC Time Stamp 13 SEP 2020 05:22

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**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

98.1 °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

14 SEP 2020 02:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 16:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:34:57

**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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 23:23

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**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

10 SEP 2020 18:24

PC Open Date & Time

10 SEP 2020 18:06

PC Close Date & Time

10 SEP 2020 20:36

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

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

30

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 03:59

PC Open Date & Time

10 SEP 2020 21:31

PC Close Date & Time

11 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**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 ☐

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

30

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

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

Yes ☒

No ☐

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

40

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 04:30

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:34:57

**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

13 SEP 2020 05:24

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**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

14 SEP 2020 02:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:34:57

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:34:57

**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

15 SEP 2020 16:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:34:57

| TIMEPOINT                                                                                  | DAY 7                                 |
|--------------------------------------------------------------------------------------------|---------------------------------------|
| Please record - <b>PAIN AT INJECTION SITE.</b>                                             | None <input checked="" type="radio"/> |
| Please select one response below                                                           |                                       |
| Does not interfere with activity                                                           | <input type="radio"/>                 |
| Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity      | <input type="radio"/>                 |
| Any use of prescription pain reliever or prevents daily activity                           | <input type="radio"/>                 |
| Is there any <b>REDNESS AT INJECTION SITE?</b>                                             | Yes <input type="radio"/>             |
|                                                                                            | No <input checked="" type="radio"/>   |
| Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>                                   | Yes <input type="radio"/>             |
|                                                                                            | No <input checked="" type="radio"/>   |
| Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>                              | None <input checked="" type="radio"/> |
| Please select one response below                                                           |                                       |
| Does not interfere with activity                                                           | <input type="radio"/>                 |
| Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity | <input type="radio"/>                 |
| Any use of prescription pain reliever or prevents daily activity                           | <input type="radio"/>                 |
| PC Time Stamp                                                                              | 16 SEP 2020 23:24                     |
| PC Open Date & Time                                                                        | 16 SEP 2020 12:00                     |
| PC Close Date & Time                                                                       | 17 SEP 2020 11:59                     |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**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 ☐

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

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

No ☒  
Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 10 SEP 2020 18:25 |
| PC Open Date & Time  | 10 SEP 2020 18:06 |
| PC Close Date & Time | 10 SEP 2020 20:36 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

**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 ☐

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 11 SEP 2020 04:01 |
| PC Open Date & Time  | 10 SEP 2020 21:31 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 12 SEP 2020 04:31 |
| PC Open Date & Time          | 11 SEP 2020 12:00 |
| PC Close Date & Time         | 12 SEP 2020 11:59 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 13 SEP 2020 05:25 |
| PC Open Date & Time          | 12 SEP 2020 12:00 |
| PC Close Date & Time         | 13 SEP 2020 11:59 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**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 ☒

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 14 SEP 2020 02:12 |
| PC Open Date & Time          | 13 SEP 2020 12:00 |
| PC Close Date & Time         | 14 SEP 2020 11:59 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 15 SEP 2020 16:53 |
| PC Open Date & Time          | 15 SEP 2020 12:00 |
| PC Close Date & Time         | 16 SEP 2020 11:59 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 16 SEP 2020 23:24 |
| PC Open Date & Time          | 16 SEP 2020 12:00 |
| PC Close Date & Time         | 17 SEP 2020 11:59 |

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

17 SEP 2020 23:22

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:34:57

|                                                                                                         |                                                                  |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                        | DAY 8                                                            |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp                                                                                           | 17 SEP 2020 23:22                                                |
| PC Open Date & Time                                                                                     | 17 SEP 2020 12:00                                                |
| PC Close Date & Time                                                                                    | 18 SEP 2020 11:59                                                |

US3342239

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

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

US3342239

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342239

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342239

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 13 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                                                      | VISIT2                                  |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| 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)    | 13 OCT 2020                               |
| Time of assessment (00:00-23:59)    | 14:27 (24 HR)                             |
| Vital Signs Date and Time (derived) | 13 OCT 2020 14:27                         |
| Temperature (xxx.x)                 | 98.0 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |                                           |
| Pulse (xxx)                         | 75 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 12 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 102 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 63 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

|                                     |                                            |
|-------------------------------------|--------------------------------------------|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input type="radio"/>                  |
|                                     | No <input checked="" type="radio"/>        |
| Date of assessment (dd MMM yyyy)    |                                            |
| Time of assessment (00:00-23:59)    |                                            |
| Vital Signs Date and Time (derived) |                                            |
| Temperature (xxx.x)                 |                                            |
| Route of measurement                | Oral <input type="radio"/>                 |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |                                            |
| Pulse (xxx)                         |                                            |
| Pulse units                         |                                            |
| Respiratory Rate (xxx)              |                                            |
| Respiratory Rate units              |                                            |
| Systolic Blood Pressure (xxx)       |                                            |
| Systolic Blood Pressure units       |                                            |
| Diastolic Blood Pressure (xxx)      |                                            |
| Diastolic Blood Pressure units      |                                            |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

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.*

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

Was study treatment given? Yes ☐ No ☒

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

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify SUBJECT HAD AE OF HEAD TRAUMA FOLLOWING PHLEBOTOMY ATTEMPT. BLOOD AND NP SWABS NOT COLLECTED, IP NOT ADMINISTERED

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

What was the treatment time? (00:00-23:59) \_\_\_\_\_

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3342239

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

Collection date (dd MMM yyyy)

| Lab Test              | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
|-----------------------|---------------------------|---------------------------------|------------------------------------|
| Nasopharyngeal Swab 1 | No                        |                                 |                                    |
| Nasopharyngeal Swab 2 | No                        |                                 |                                    |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

3X ATTEMPTED CALLS

UNSUCCESSFUL

If Contact Not Made, please provide Comments

US3342239

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

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

US3342239

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

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

US3342239

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID VISIT3

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3342239

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

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.*

US3342239

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3342239

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:18:25

Generated On: 11 Aug 2021 22:34:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342239

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:34:57

|                                                                                                                                                                                 |                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                                                                                                | DAY 64                                                           |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                  |
| Date and time of submission                                                                                                                                                     | 13 NOV 2020 16:27:44                                             |
| Patient Cloud Open Date & Time                                                                                                                                                  | 10 NOV 2020 00:01                                                |
| Patient Cloud Close Date & Time                                                                                                                                                 | 14 NOV 2020 23:59                                                |

US3342239

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 11 Aug 2021 22:34:57**

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
|                                                                                                                   |                                                                                                                                                                |                           |
|                                                                                                                   |                                                                                                                                                                |                           |

US3342239

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:57

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*

US3342239

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342239

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:34:57

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

US3342239

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:34:57

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3342239

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

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_

US3342239

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

Form: Unblinding

Generated On: 11 Aug 2021 22:34:57

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

US3342239

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

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

|                                        |       |
|----------------------------------------|-------|
| Collection date ( <i>dd MMM yyyy</i> ) | _____ |
| Collection time ( <i>00:00-23:59</i> ) | _____ |
| Collection date and time (derived)     | _____ |

US3342239

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:34:57

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00 - 23:59*)

Collection Date and Time (derived)

US3342239

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

AEID

Adverse event

HEAD TRAUMA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

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

US3342239

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

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

**Data signed:** (b) (4) 12 Mar 2021 23:18:14

**Generated On: 11 Aug 2021 22:34:57**

---

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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US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Name of Medication BUSPIRONE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intramuscular            | <input type="radio"/>            |
|                                                    | Respiratory (Inhalation) | <input type="radio"/>            |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN JUN 2018              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?                                           | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | UN FEB 2019                      |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 2                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input checked="" type="radio"/> |

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

|                                                    |                                      |                       |
|----------------------------------------------------|--------------------------------------|-----------------------|
|                                                    | 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 JUN 2018                          |                       |
| Start date completely unknown                      | False                                |                       |
| Ongoing?                                           | Yes <input type="radio"/>            |                       |
|                                                    | No <input checked="" type="radio"/>  |                       |
| <hr/>                                              |                                      |                       |
| If not Ongoing, End date (dd MMM yyyy)             |                                      | UN FEB 2019           |
| <hr/>                                              |                                      |                       |
| Was this medication taken for solicited event?     | Yes <input type="radio"/>            |                       |
|                                                    | No <input checked="" type="radio"/>  |                       |
| <hr/>                                              |                                      |                       |
| Separate Dosage Number (derived)                   | 2                                    |                       |
| Interval Dosage Unit Number (derived)              | 1                                    |                       |
| Interval Dosage Definition (derived)               | 802 <input type="radio"/>            |                       |
|                                                    | 803 <input type="radio"/>            |                       |
|                                                    | 804 <input checked="" type="radio"/> |                       |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Name of Medication BUSPAR

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | 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 JAN 2018              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?                                           | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| <hr/>                                              |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy)             | UN JUN 2018              |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| <hr/>                                              |                          |                                  |
| Separate Dosage Number (derived)                   | 2                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input checked="" type="radio"/> |

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Name of Medication NAPROXEN

Prophylaxis Yes ☐  
No ☒

Indication INJECTION SITE PAIN

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

|                                                    |                          |                                     |
|----------------------------------------------------|--------------------------|-------------------------------------|
|                                                    | Intramuscular            | <input type="checkbox"/>            |
|                                                    | Respiratory (Inhalation) | <input type="checkbox"/>            |
|                                                    | Intralesional            | <input type="checkbox"/>            |
|                                                    | Intraperitoneal          | <input type="checkbox"/>            |
|                                                    | Nasal                    | <input type="checkbox"/>            |
|                                                    | Vaginal                  | <input type="checkbox"/>            |
|                                                    | Rectal                   | <input type="checkbox"/>            |
|                                                    | Intravenous              | <input type="checkbox"/>            |
|                                                    | Intravenous Bolus        | <input type="checkbox"/>            |
|                                                    | Intravenous Drip         | <input type="checkbox"/>            |
|                                                    | Other                    | <input type="checkbox"/>            |
| <hr/>                                              |                          |                                     |
| If route of administration is Other, specify <hr/> |                          |                                     |
| Start date (dd MMM yyyy)                           | 11 SEP 2020              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?                                           | Yes                      | <input type="checkbox"/>            |
|                                                    | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                              |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)             | 12 SEP 2020              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input checked="" type="checkbox"/> |
|                                                    | No                       | <input type="checkbox"/>            |
| <hr/>                                              |                          |                                     |
| Separate Dosage Number (derived)                   | <hr/>                    |                                     |
| Interval Dosage Unit Number (derived)              | <hr/>                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|                                                    | 803                      | <input type="checkbox"/>            |
|                                                    | 804                      | <input type="checkbox"/>            |

US3342239

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Data signed:** (b) (4) 12 Mar 2021 23:18:14

**Generated On: 11 Aug 2021 22:34:57**

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[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

---

**If yes, please complete Concomitant Procedures form.**

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US3342239

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

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Date of dosing discontinuation (dd MMM yyyy) 13 OCT 2020

---

Primary reason for dosing discontinuation

|                                                |                                  |
|------------------------------------------------|----------------------------------|
| AE (specify)                                   | <input checked="" type="radio"/> |
| SAE (specify)                                  | <input type="radio"/>            |
| Death                                          | <input type="radio"/>            |
| Lost To Follow-up                              | <input type="radio"/>            |
| Physician decision (specify)                   | <input type="radio"/>            |
| Pregnancy                                      | <input type="radio"/>            |
| Protocol deviation (specify)                   | <input type="radio"/>            |
| Study Terminated By Sponsor                    | <input type="radio"/>            |
| Withdrawal of consent by participant (specify) | <input type="radio"/>            |
| Due to SARS-COV-2                              | <input type="radio"/>            |
| Other                                          | <input type="radio"/>            |

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

---

AE #1

US3342239

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 12 Mar 2021 23:18:14

Generated On: 11 Aug 2021 22:34:57

Date of study discontinuation/completion (dd MMM yyyy) 11 NOV 2020

Reason for discontinuation

|                                                |                                     |
|------------------------------------------------|-------------------------------------|
| AE (specify)                                   | <input type="checkbox"/>            |
| SAE (specify)                                  | <input type="checkbox"/>            |
| Complete                                       | <input type="checkbox"/>            |
| Death                                          | <input type="checkbox"/>            |
| Lost To Follow-up                              | <input checked="" type="checkbox"/> |
| Physician decision (specify)                   | <input type="checkbox"/>            |
| Pregnancy                                      | <input type="checkbox"/>            |
| Protocol deviation (specify)                   | <input type="checkbox"/>            |
| Study Terminated By Sponsor                    | <input type="checkbox"/>            |
| Withdrawal of consent by participant (specify) | <input type="checkbox"/>            |
| Other                                          | <input type="checkbox"/>            |

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 | <input type="checkbox"/> |
| Unknown       | <input type="checkbox"/> |
| Other         | <input type="checkbox"/> |

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

|         |                          |
|---------|--------------------------|
| Yes     | <input type="checkbox"/> |
| No      | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |

Audit

US3342239 (Prod: Tekton Research- Austin)

US3342239

Form: Participant Creation

Generated On: 11 Aug 2021 22:34:57

[Participant ID](#)

| Audit                     | User                                                   | Time (GMT)           |
|---------------------------|--------------------------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                                       | 28 Apr 2021 15:32:05 |
| DataPoint Verified.       | (b) (4), (b) (6)                                       | 31 Mar 2021 17:12:47 |
| User signature succeeded. | Paul Pickrell (b) (4)                                  | 12 Mar 2021 23:18:15 |
| User entered 'US3342239'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 10 Sep 2020 22:04:27 |

US3342239

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:34:57**

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:05 |
|                   |                  |                      |

US3342239

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Morgan Schulle (b) (4) | 10 Sep 2020 22:29:34 |

US3342239

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                                                   | Time (GMT)           |
|----------------------------|--------------------------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                                       | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)                                  | 12 Mar 2021 23:18:15 |
| User entered '10 SEP 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 10 Sep 2020 22:04:28 |

US3342239

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.      | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Clinic (Clinic)' | Morgan Schulle (b) (4) | 10 Sep 2020 22:29:34 |

US3342239

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:34:57**

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'SCRN' | System           | 10 Sep 2020 22:29:34 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[Date of Birth \(MMM yyyy\)](#)

| Audit                      | User                                                   | Time (GMT)           |
|----------------------------|--------------------------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                                       | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)                                  | 12 Mar 2021 23:18:15 |
| User entered (b) (6) 1990' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 10 Sep 2020 22:04:29 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[Age](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '30'         | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'YEARS' | System           | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '30' | System           | 10 Sep 2020 22:30:34 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

Sex

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Female (F)' | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[Ethnicity](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

White

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '1'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[Black](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[Asian](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[American Indian or Alaska Native](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[Other](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

If race is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[Unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:34:57

[Not reported](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:10 |

US3342239

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:57

Date of Informed Consent (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '10 Sep 2020' | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:34 |

US3342239

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:34:57**

[Month and Year of Informed Consent \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'Sep 2020' | System           | 10 Sep 2020 22:30:34 |

US3342239

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:34:57**

[Year of Informed Consent \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '2020' | System           | 10 Sep 2020 22:30:34 |

US3342239

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:34:57**

[Protocol Version](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.      | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Amendment 3 (3)' | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:34 |

US3342239

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:34:57

[Was participant enrolled in the study?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:34 |

US3342239

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:34:57**

[If No, indicate reason for screen fail](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:34 |

US3342239

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:34:57**

If reason for screen fail is Other, specify

| Audit                     | User                                         | Time (GMT)           |
|---------------------------|----------------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)                        | 12 Mar 2021 23:18:15 |
| User entered empty.       | (b) (4)<br>Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:30:34 |

US3342239

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:34:57**

[Was this participant screened previously?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:34 |

US3342239

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:34:57**

[If Yes, previous participant number](#)

| Audit                     | User                                                   | Time (GMT)           |
|---------------------------|--------------------------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                                       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)                                  | 12 Mar 2021 23:18:15 |
| User entered empty.       | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 10 Sep 2020 22:04:28 |

US3342239

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:34:57**

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '1'  | System           | 10 Sep 2020 22:30:41 |

US3342239

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:34:57

[Did the participant meet all eligibility criteria?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Morgan Schulle (b) (4) | 10 Sep 2020 22:30:41 |

US3342239

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:34:57

[Were any significant conditions reported?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | (b) (4)<br>Andrew Bell (b) (4) | 10 Sep 2020 22:50:22 |

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:57

[Condition](#)

| Audit                                                                                                                                                                                                                              | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                  | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                                                                                                                                                                          | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0. | Coder Import (b) (4)  | 10 Sep 2020 22:52:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                       | Coder Import (b) (4)  | 10 Sep 2020 22:52:43 |
| Data point term sent to Coder                                                                                                                                                                                                      | System                | 10 Sep 2020 22:51:28 |
| User entered 'bilateral tubal ligation'                                                                                                                                                                                            | Andrew Bell (b) (4)   | 10 Sep 2020 22:50:57 |

US3342239

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)               | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)          | 12 Mar 2021 23:18:15 |
| User entered '02 Mar 2012' | (b) (4)<br>Andrew Bell (b) (4) | 10 Sep 2020 22:50:57 |

US3342239

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:34:57

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|-------------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)                     | 12 Mar 2021 23:18:15 |
| User entered '0'          | (b) (4)<br>Andrew Bell (b) (4)<br>(b) (4) | 10 Sep 2020 22:50:57 |

US3342239

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Condition ongoing at study entry](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Andrew Bell (b) (4)   | 10 Sep 2020 22:50:57 |

US3342239

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:34:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '02 Mar 2012' | Andrew Bell (b) (4)   | 10 Sep 2020 22:50:57 |

US3342239

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop date completely unknown](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:18:15 |
| User entered '0'          | (b) (4)<br>Andrew Bell (b) (4) | 10 Sep 2020 22:50:57 |

US3342239

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'Mar 2012' | System           | 10 Sep 2020 22:50:57 |

US3342239

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '2012' | System           | 10 Sep 2020 22:50:57 |

US3342239

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'Mar 2012' | System           | 10 Sep 2020 22:50:57 |

US3342239

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '2012' | System           | 10 Sep 2020 22:50:57 |

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:57

[Condition](#)

| Audit                                                                                                                                                                                 | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                                     | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                                                                                                                             | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\23.0. | Coder Import (b) (4)  | 10 Sep 2020 22:52:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                           | Coder Import (b) (4)  | 10 Sep 2020 22:52:44 |
| Data point term sent to Coder                                                                                                                                                         | System                | 10 Sep 2020 22:51:28 |
| User entered 'gallstones'                                                                                                                                                             | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:16 |

US3342239

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'UN Mar 2019' | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:16 |

US3342239

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date completely unknown](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:18:15 |
| User entered '0'          | (b) (4)<br>Andrew Bell (b) (4) | 10 Sep 2020 22:51:16 |

US3342239

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:34:57

[Condition ongoing at study entry](#)

| Audit                                                                                                                                                                                                                                                                                       | User                           | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                           | (b) (4), (b) (6)               | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                                                                                                                                                                                                                                   | Paul Pickrell (b) (4)          | 12 Mar 2021 23:18:15 |
| Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration.             | (b) (4)<br>(b) (4), (b) (6)    | 08 Nov 2020 12:45:55 |
| ' canceled (Site from DM).                                                                                                                                                                                                                                                                  |                                |                      |
| User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration. | (b) (4), (b) (6)               | 16 Oct 2020 15:24:56 |
| ' (Site from DM).                                                                                                                                                                                                                                                                           |                                |                      |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                      | Andrew Bell (b) (4)<br>(b) (4) | 10 Sep 2020 22:51:16 |

US3342239

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:34:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:16 |

US3342239

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '0'          | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:16 |

US3342239

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'Mar 2019' | System           | 10 Sep 2020 22:51:16 |

US3342239

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '2019' | System           | 10 Sep 2020 22:51:16 |

US3342239

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered empty. | System           | 10 Sep 2020 22:51:16 |

US3342239

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered empty. | System           | 10 Sep 2020 22:51:16 |

US3342239

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:34:57

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                                 | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                     | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                                                                                                                                                                                                                                             | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc disorder, LLT: Disc lesion lumbar - version MedDRA\23.0. | Coder Import (b) (4)  | 11 Sep 2020 20:54:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                                                                                | Coder Import (b) (4)  | 11 Sep 2020 20:54:39 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                         | System                | 10 Sep 2020 22:52:32 |
| User entered 'L5 defective disc'                                                                                                                                                                                                                                                                      | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:37 |

US3342239

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'UN Mar 2019' | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:37 |

US3342239

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date completely unknown](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:18:15 |
| User entered '0'          | (b) (4)<br>Andrew Bell (b) (4) | 10 Sep 2020 22:51:37 |

US3342239

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Condition ongoing at study entry](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:37 |

US3342239

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:34:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:37 |

US3342239

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop date completely unknown](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:18:15 |
| User entered '0'          | (b) (4)<br>Andrew Bell (b) (4) | 10 Sep 2020 22:51:37 |

US3342239

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'Mar 2019' | System           | 10 Sep 2020 22:51:37 |

US3342239

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '2019' | System           | 10 Sep 2020 22:51:37 |

US3342239

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered empty. | System           | 10 Sep 2020 22:51:37 |

US3342239

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered empty. | System           | 10 Sep 2020 22:51:37 |

US3342239

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:34:57

[Condition](#)

| Audit                                                                                                                                                              | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                  | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                                                                                                          | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4)  | 10 Sep 2020 22:53:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                       | Coder Import (b) (4)  | 10 Sep 2020 22:53:44 |
| Data point term sent to Coder                                                                                                                                      | System                | 10 Sep 2020 22:52:29 |
| User entered 'anxiety'                                                                                                                                             | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:55 |

US3342239

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'UN Jan 2018' | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:55 |

US3342239

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '0'          | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:55 |

US3342239

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Condition ongoing at study entry](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:55 |

US3342239

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:34:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:51:55 |

US3342239

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop date completely unknown](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:18:15 |
| User entered '0'          | (b) (4)<br>Andrew Bell (b) (4) | 10 Sep 2020 22:51:55 |

US3342239

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'Jan 2018' | System           | 10 Sep 2020 22:51:55 |

US3342239

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '2018' | System           | 10 Sep 2020 22:51:55 |

US3342239

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered empty. | System           | 10 Sep 2020 22:51:55 |

US3342239

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered empty. | System           | 10 Sep 2020 22:51:55 |

US3342239

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:34:57

[Condition](#)

| Audit                                                                                                                                                                                                                                                                              | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                                                                                                                                                                                                                          | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| 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. ' canceled (Site from DM).    | (b) (4), (b) (6)      | 08 Nov 2020 12:46:04 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM). | (b) (4), (b) (6)      | 16 Oct 2020 15:25:55 |
| 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)  | 10 Sep 2020 22:53:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                        | Coder Import (b) (4)  | 10 Sep 2020 22:53:44 |
| Data point term sent to Coder                                                                                                                                                                                                                                                      | System                | 10 Sep 2020 22:52:32 |
| User entered 'hypertension'                                                                                                                                                                                                                                                        | Andrew Bell (b) (4)   | 10 Sep 2020 22:52:12 |

US3342239

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'UN Jun 2018' | Andrew Bell (b) (4)   | 10 Sep 2020 22:52:12 |

US3342239

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date completely unknown](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:18:15 |
| User entered '0'          | (b) (4)<br>Andrew Bell (b) (4) | 10 Sep 2020 22:52:12 |

US3342239

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:34:57**

[Condition ongoing at study entry](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | (b) (4)<br>Andrew Bell (b) (4) | 10 Sep 2020 22:52:12 |

US3342239

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:34:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:52:12 |

US3342239

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop date completely unknown](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:18:15 |
| User entered '0'          | (b) (4)<br>Andrew Bell (b) (4) | 10 Sep 2020 22:52:12 |

US3342239

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:34:57**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'Jun 2018' | System           | 10 Sep 2020 22:52:12 |

US3342239

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:34:57**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '2018' | System           | 10 Sep 2020 22:52:12 |

US3342239

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered empty. | System           | 10 Sep 2020 22:52:12 |

US3342239

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:34:57**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered empty. | System           | 10 Sep 2020 22:52:12 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User entered '10 Sep 2020' | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |

US3342239

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:34:57**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '16:48'      | Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |

US3342239

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:34:57**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '10 Sep 2020 16:48' | System           | 10 Sep 2020 22:36:28 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

Height (xxx.x)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User entered '162.5' cm   | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |
| DataPoint set to visible. | (b) (4)<br>System                 | 10 Sep 2020 22:30:41 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

Weight (xxx.x)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User entered '64.2' kg    | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |
| DataPoint set to visible. | (b) (4)<br>System                 | 10 Sep 2020 22:30:41 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '24.31243'   | System           | 10 Sep 2020 22:36:28 |
| DataPoint set to visible. | System           | 10 Sep 2020 22:30:41 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'kg/m2'      | System           | 10 Sep 2020 22:36:28 |
| DataPoint set to visible. | System           | 10 Sep 2020 22:30:41 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

Temperature (xxx.x)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered missing code ND - Not Done. | Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Route of measurement](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Pulse \(xxx\)](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered missing code ND - Not Done. | Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |

US3342239

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:34:57**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'bpm' | System           | 10 Sep 2020 22:36:28 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Respiratory Rate \(xxx\)](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered missing code ND - Not Done. | Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |

US3342239

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:34:57**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'breaths/min' | System           | 10 Sep 2020 22:36:28 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Systolic Blood Pressure \(xxx\)](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered missing code ND - Not Done. | Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |

US3342239

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:34:57**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'mmHg' | System           | 10 Sep 2020 22:36:28 |

US3342239

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:34:57**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered missing code ND - Not Done. | Morgan Schulle (b) (4) | 10 Sep 2020 22:36:28 |

US3342239

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:34:57**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'mmHg' | System           | 10 Sep 2020 22:36:28 |

US3342239

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:34:57**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |

US3342239

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |

US3342239

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:34:57**

[Was the physical examination performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Morgan Schulle (b) (4) | 10 Sep 2020 22:37:03 |

US3342239

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:57

Date of examination (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User entered '10 Sep 2020' | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:37:03 |

US3342239

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:34:57**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '10 Sep 2020' | Morgan Schulle (b) (4) | 10 Sep 2020 22:37:48 |

US3342239

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:34:57

[Is the participant of childbearing potential?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:37:48 |

US3342239

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:34:57**

[If No, what is the reason?](#)

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                              | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Surgically sterile (SURGICALLY STERILE)' | Morgan Schulle (b) (4) | 10 Sep 2020 22:37:48 |

US3342239

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:34:57**

[If Partner medically sterile or Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User entered empty.       | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:37:48 |

US3342239

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:34:57**

[If Surgically sterile, date of surgery \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User entered '02 Mar 2012' | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:37:48 |

US3342239

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:34:57**

[Date of surgery unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:37:48 |

US3342239

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:34:57**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Morgan Schulle (b) (4) | 10 Sep 2020 22:37:48 |

US3342239

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:34:57**

[Date of last menstruation unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:37:48 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:34:57**

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:34:57**

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:34:57**

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:34:57**

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:34:57**

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

[Other](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

[Specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

No Risk Identified

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit                     | User                                         | Time (GMT)           |
|---------------------------|----------------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)                        | 12 Mar 2021 23:18:15 |
| User entered '0'          | (b) (4)<br>Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '1'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

[Resides in a single family home](#) (i.e., detached housing)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

[Other](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:34:57

[Specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Morgan Schulle (b) (4) | 10 Sep 2020 22:38:17 |

US3342239

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'Yes (Y)'    | Morgan Schulle (b) (4) | 10 Sep 2020 22:39:53 |

US3342239

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered '10 Sep 2020' | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:39:53 |

US3342239

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.      | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'Clinic (Clinic)' | Morgan Schulle (b) (4) | 10 Sep 2020 22:39:53 |

US3342239

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'VISIT1' | System           | 10 Sep 2020 22:39:53 |

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:57

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

| Audit                      | User                                                   | Time (GMT)           |
|----------------------------|--------------------------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                                       | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)                                  | 12 Mar 2021 23:18:26 |
| User entered '10 SEP 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 10 Sep 2020 22:19:21 |

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:57

[What was the participant's randomization number?](#)

| Audit                     | User                                                   | Time (GMT)           |
|---------------------------|--------------------------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                                       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)                                  | 12 Mar 2021 23:18:26 |
| User entered '113263'     | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 10 Sep 2020 22:19:21 |

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:57

[In what Cohort was the participant enrolled?](#)

| Audit                                                 | User                                                   | Time (GMT)           |
|-------------------------------------------------------|--------------------------------------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                                       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                             | Paul Pickrell (b) (4)                                  | 12 Mar 2021 23:18:26 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 10 Sep 2020 22:19:21 |

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:57

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:40:06 |

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:57

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:40:06 |

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:57

Severe obesity (body mass index > or = 40kg/m2

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:40:06 |

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:57

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:40:06 |

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:57

[Liver Disease](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:40:06 |

US3342239

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:34:57

Human Immunodeficiency Virus (HIV) infection

| Audit                                                                                                                | User                                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| Data hard locked.                                                                                                    | (b) (4), (b) (6)                     | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                                                            | Paul Pickrell (b) (4)                | 12 Mar 2021 23:18:26 |
| User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).              | (b) (4)<br>(b) (4), (b) (6)          | 07 Dec 2020 16:25:26 |
| Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Answered' (Site from DM). | Olivia Hapanowicz (b) (4)            | 07 Dec 2020 14:21:10 |
| User entered 'No (N)'                                                                                                | (b) (4)<br>Olivia Hapanowicz (b) (4) | 07 Dec 2020 14:21:06 |
| User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).              | (b) (4)<br>(b) (4), (b) (6)          | 02 Dec 2020 22:29:02 |
| Amendment Manager: DataPoint set to visible.                                                                         | System                               | 19 Sep 2020 06:05:57 |
| Amendment Manager inserted this DataPoint.                                                                           | System                               | 19 Sep 2020 06:05:56 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:57

[Height](#)

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered missing code ND - Not Done. | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:57

[Weight](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered missing code ND - Not Done. | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:57

[Height](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered missing code ND - Not Done. | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:57

[Weight](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered missing code ND - Not Done. | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Timepoint](#)

| Audit                                            | User                              | Time (GMT)           |
|--------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'Yes (Y)'    | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                                         | Time (GMT)           |
|----------------------------|----------------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                             | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)                        | 12 Mar 2021 23:18:26 |
| User entered '10 Sep 2020' | (b) (4)<br>Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

Time of assessment (00:00-23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered '16:48'      | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '10 Sep 2020 16:48' | System           | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered '98.7' F     | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Route of measurement](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'Oral (Oral)' | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[If Other, specify](#)

| Audit                     | User                                         | Time (GMT)           |
|---------------------------|----------------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)                        | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Pulse \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered '71'         | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'bpm' | System           | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered '16'         | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'breaths/min' | System           | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

Systolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered '112'        | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'mmHg' | System           | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered '74'         | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'mmHg' | System           | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:57

[Height](#)

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered missing code ND - Not Done. | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:34:57

[Weight](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered missing code ND - Not Done. | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Timepoint](#)

| Audit                                              | User                              | Time (GMT)           |
|----------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Were vital signs assessed?](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                      | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                              | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                | 10 Sep 2020 23:21:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 10 Sep 2020 23:21:33 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | (b) (4), (b) (6)       | 10 Sep 2020 23:21:33 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 10 Sep 2020 22:41:21 |
| User entered empty.                                                                    | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

Date of assessment (*dd MMM yyyy*)

| Audit                                                          | User                              | Time (GMT)           |
|----------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered '10 Sep 2020' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 10 Sep 2020 23:21:33 |
| User entered empty.                                            | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

Time of assessment (00:00-23:59)

| Audit                                                    | User                              | Time (GMT)           |
|----------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                        | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered '18:17' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 10 Sep 2020 23:21:33 |
| User entered empty.                                      | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '10 Sep 2020 18:17' | System           | 10 Sep 2020 23:21:33 |
| User entered empty.              | System           | 10 Sep 2020 22:41:21 |

US3342239

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

Temperature (xxx.x)

| Audit                                                     | User                              | Time (GMT)           |
|-----------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                         | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                 | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered '98.9' F reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 10 Sep 2020 23:21:33 |
| User entered empty.                                       | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Route of measurement](#)

| Audit                                                          | User                              | Time (GMT)           |
|----------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 10 Sep 2020 23:21:33 |
| User entered empty.                                            | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[If Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Pulse \(xxx\)](#)

| Audit                                                 | User                              | Time (GMT)           |
|-------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                             | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered '69' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 10 Sep 2020 23:21:33 |
| User entered empty.                                   | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'bpm'  | System           | 10 Sep 2020 23:21:33 |
| User entered empty. | System           | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Respiratory Rate \(xxx\)](#)

| Audit                                                 | User                              | Time (GMT)           |
|-------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                             | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered '16' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 10 Sep 2020 23:21:33 |
| User entered empty.                                   | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'breaths/min' | System           | 10 Sep 2020 23:21:33 |
| User entered empty.        | System           | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

Systolic Blood Pressure (xxx)

| Audit                                                  | User                              | Time (GMT)           |
|--------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                              | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered '112' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 10 Sep 2020 23:21:33 |
| User entered empty.                                    | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'mmHg' | System           | 10 Sep 2020 23:21:33 |
| User entered empty. | System           | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

Diastolic Blood Pressure (xxx)

| Audit                                                                                                                                                                                                                                                    | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                        | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                                                                                                                                                                                                | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                                                     | (b) (4)<br>(b) (4), (b) (6)       | 25 Sep 2020 20:13:33 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Deemed clinically insignificant by investigator' (Site from System). | (b) (4), (b) (6)                  | 25 Sep 2020 14:27:38 |
| Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                                  | System                            | 17 Sep 2020 00:32:56 |
| User entered '54' reason for change: Data Entry Error                                                                                                                                                                                                    | (b) (4), (b) (6)                  | 10 Sep 2020 23:21:33 |
| User entered empty.                                                                                                                                                                                                                                      | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'mmHg' | System           | 10 Sep 2020 23:21:33 |
| User entered empty. | System           | 10 Sep 2020 22:41:21 |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:57

[Was the physical examination performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:26 |

US3342239

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:57

Date of examination (*dd MMM yyyy*)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:41:26 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[Was study treatment given?](#)

| Audit                                                                                                                                                                                             | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                 | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                                                                                                                                         | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).             | (b) (4)                | 10 Sep 2020 23:01:18 |
| Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System). | System                 | 10 Sep 2020 23:01:18 |
| User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).             | System                 | 10 Sep 2020 22:41:35 |
| User entered 'Yes (Y)'                                                                                                                                                                            | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:35 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[If No, reason not given](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:35 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:35 |

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 10 Sep 2020 22:41:35 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '10 Sep 2020' | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:35 |

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                                                    | User                              | Time (GMT)           |
|----------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                        | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User entered '17:46' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 10 Sep 2020 23:01:18 |
| User entered empty.                                      | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:35 |

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '10 Sep 2020 17:46' | System           | 10 Sep 2020 23:01:18 |
| User entered empty.              | System           | 10 Sep 2020 22:41:35 |

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[Which arm was used to give treatment?](#)

| Audit                                                                  | User                              | Time (GMT)           |
|------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                      | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                              | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 10 Sep 2020 23:01:18 |
| User entered empty.                                                    | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:35 |

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'ONCE' | System           | 10 Sep 2020 22:41:35 |

US3342239

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered 'INTRAMUSCULAR' | System           | 10 Sep 2020 22:41:35 |

US3342239

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:43 |

US3342239

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

Collection date (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '10 Sep 2020' | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:43 |

US3342239

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

Collection time (00:00-23:59)

| Audit                                                                     | User                   | Time (GMT)           |
|---------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                 | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4)                | 10 Sep 2020 23:13:03 |
| User entered '17:18' reason for change: Data Entry Error                  | System                 | 10 Sep 2020 23:13:03 |
| User opened query 'Data is required. Please provide.' (Site from System). | Andrew Bell (b) (4)    | 10 Sep 2020 23:13:03 |
| User entered empty.                                                       | (b) (4)                | 10 Sep 2020 22:41:43 |
|                                                                           | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:43 |
|                                                                           | (b) (4)                |                      |

US3342239

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '10 Sep 2020 17:18' | System           | 10 Sep 2020 23:13:03 |
| User entered empty.              | System           | 10 Sep 2020 22:41:43 |

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:34:57

Collection date (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User entered '10 Sep 2020' | (b) (4)<br>Morgan Schulle (b) (4) | 10 Sep 2020 22:41:51 |

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:57

[Lab Test](#)

| Audit                                                        | User                              | Time (GMT)           |
|--------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                            | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:51 |

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:57

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:51 |

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:57

Collection time (00:00 - 23:59)

| Audit                                                                                                                                                    | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                                                                                        | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded.                                                                                                                                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).             | (b) (4)                | 10 Sep 2020 23:13:13 |
| Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System). | System                 | 10 Sep 2020 23:13:13 |
| User entered '17:20' reason for change: Data Entry Error                                                                                                 | Andrew Bell (b) (4)    | 10 Sep 2020 23:13:13 |
| User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).             | (b) (4)                | 10 Sep 2020 22:41:51 |
| User entered empty.                                                                                                                                      | System                 | 10 Sep 2020 22:41:51 |
|                                                                                                                                                          | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:51 |
|                                                                                                                                                          | (b) (4)                |                      |

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:57

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '10 Sep 2020 17:20' | System           | 10 Sep 2020 23:13:13 |
| User entered empty.              | System           | 10 Sep 2020 22:41:51 |

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:57

[Lab Test](#)

| Audit                                                        | User                              | Time (GMT)           |
|--------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                            | (b) (4), (b) (6)                  | 28 Apr 2021 12:56:45 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Morgan Schulle (b) (4)<br>(b) (4) | 10 Sep 2020 22:41:51 |

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:57

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:51 |

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:57

Collection time (00:00 - 23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:51 |

US3342239

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:57

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered empty. | System           | 10 Sep 2020 22:41:51 |

US3342239

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Morgan Schulle (b) (4) | 10 Sep 2020 22:41:57 |

US3342239

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '1'  | System           | 10 Sep 2020 22:41:57 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                                                                | User             | Time (GMT)           |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.                                                   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:22:34', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'f8f4faa6-3b6b-4af1-836f-c41d9697345a' | System           | 10 Sep 2020 23:22:59 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System           | 10 Sep 2020 23:22:59 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:22:42', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'f8f4faa6-3b6b-4af1-836f-c41d9697345a' | System           | 10 Sep 2020 23:22:59 |
| User entered '98.9'                                                                                                                                                                                                                        | System           | 10 Sep 2020 23:22:59 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:22:46', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'f8f4faa6-3b6b-4af1-836f-c41d9697345a' | System           | 10 Sep 2020 23:22:59 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 10 Sep 2020 23:22:59 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:22:55', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'f8f4faa6-3b6b-4af1-836f-c41d9697345a' | System           | 10 Sep 2020 23:22:59 |
| User entered '10 Sep 2020 18:22'                                                                                                                                                                                                           | System           | 10 Sep 2020 23:22:59 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '10 Sep 2020 18:06' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '10 Sep 2020 20:36' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                                             | User             | Time (GMT)           |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.                                | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 1, after vaccination (at home)' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:52:47', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '12238395-2448-4c7a-9a8c-4de28fa51d8d' | System           | 11 Sep 2020 08:53:18 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System           | 11 Sep 2020 08:53:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:52:54', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '12238395-2448-4c7a-9a8c-4de28fa51d8d' User entered '98.4' | System           | 11 Sep 2020 08:53:18 |
|                                                                                                                                                                                                                                                                | System           | 11 Sep 2020 08:53:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:52:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '12238395-2448-4c7a-9a8c-4de28fa51d8d' | System           | 11 Sep 2020 08:53:18 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 11 Sep 2020 08:53:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:53:15', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '12238395-2448-4c7a-9a8c-4de28fa51d8d' | System           | 11 Sep 2020 08:53:18 |
| User entered '11 Sep 2020 03:53'                                                                                                                                                                                                           | System           | 11 Sep 2020 08:53:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '10 Sep 2020 21:31' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '11 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 2' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:34:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:23:36', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae' | System           | 12 Sep 2020 09:24:41 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System           | 12 Sep 2020 09:24:41 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:34:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:23:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae' | System           | 12 Sep 2020 09:24:41 |
| User entered '98.9'                                                                                                                                                                                                                        | System           | 12 Sep 2020 09:24:41 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:23:51', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae' | System           | 12 Sep 2020 09:24:41 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System           | 12 Sep 2020 09:24:41 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | User                    | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | (b) (4), (b) (6)        | 25 Feb 2021 15:24:07 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System). | (b) (4), (b) (6)        | 05 Oct 2020 08:23:38 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:24:04', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae'                                 | Darrell O'Brien (b) (4) | 02 Oct 2020 19:40:20 |
| User entered '1'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | System                  | 12 Sep 2020 09:24:41 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | System                  | 12 Sep 2020 09:24:41 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | System                  | 12 Sep 2020 09:24:41 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:34:57

To **PREVENT** pain or fever from occurring

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | User                    | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)        | 25 Feb 2021 15:24:07 |
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System). | (b) (4), (b) (6)        | 05 Oct 2020 08:23:40 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:24:04', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae'                                   | Darrell O'Brien (b) (4) | 02 Oct 2020 19:40:34 |
| User entered '1'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | System                  | 12 Sep 2020 09:24:41 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:24:37', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '029143cd-393a-4833-9171-ed27223ff9ae' | System           | 12 Sep 2020 09:24:41 |
| User entered '12 Sep 2020 04:24'                                                                                                                                                                                                           | System           | 12 Sep 2020 09:24:41 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '11 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '12 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 3' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:34:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:21:44', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54' | System           | 13 Sep 2020 10:22:10 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System           | 13 Sep 2020 10:22:10 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:34:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:21:50', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54' | System           | 13 Sep 2020 10:22:10 |
| User entered '98.5'                                                                                                                                                                                                                        | System           | 13 Sep 2020 10:22:10 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:21:54', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54' | System           | 13 Sep 2020 10:22:10 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System           | 13 Sep 2020 10:22:10 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | User                    | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | (b) (4), (b) (6)        | 25 Feb 2021 15:24:07 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System). | (b) (4), (b) (6)        | 05 Oct 2020 08:23:44 |
| 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).                                                                                                                                                                                                                                                                            | Darrell O'Brien (b) (4) | 02 Oct 2020 19:41:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:22:01', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54'                                                                                                                                                                                                                                                                                                | (b) (4)                 |                      |
| User entered '1'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | System                  | 13 Sep 2020 10:22:10 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | System                  | 13 Sep 2020 10:22:10 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | System                  | 13 Sep 2020 10:22:10 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:34:57

To **PREVENT** pain or fever from occurring

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | User                    | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)        | 25 Feb 2021 15:24:07 |
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System). | (b) (4), (b) (6)        | 05 Oct 2020 08:23:47 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).                                                                                                                                                                                                                                                                              | Darrell O'Brien (b) (4) | 02 Oct 2020 19:41:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:22:01', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54'                                                                                                                                                                                                                                                                                                    | (b) (4)                 |                      |
| User entered '1'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | System                  | 13 Sep 2020 10:22:10 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:22:08', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68c0abe9-b458-4f9e-9a9e-04b3c5c29d54' | System           | 13 Sep 2020 10:22:10 |
| User entered '13 Sep 2020 05:22'                                                                                                                                                                                                           | System           | 13 Sep 2020 10:22:10 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '12 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '13 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 4' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:34:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:02', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '2d774c0c-7620-4014-be78-44d9e5bc307c' | System           | 14 Sep 2020 07:12:17 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System           | 14 Sep 2020 07:12:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:34:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:06', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '2d774c0c-7620-4014-be78-44d9e5bc307c' User entered '98.1' | System           | 14 Sep 2020 07:12:17 |
|                                                                                                                                                                                                                                                                | System           | 14 Sep 2020 07:12:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:10', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '2d774c0c-7620-4014-be78-44d9e5bc307c' | System           | 14 Sep 2020 07:12:17 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 14 Sep 2020 07:12:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:14', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '2d774c0c-7620-4014-be78-44d9e5bc307c' | System           | 14 Sep 2020 07:12:17 |
| User entered '14 Sep 2020 02:12'                                                                                                                                                                                                           | System           | 14 Sep 2020 07:12:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '13 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '14 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 5' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:34:57

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
|                   |                  |                      |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:34:57

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:34:57

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:34:57

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:34:57

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
|                   |                  |                      |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '14 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '15 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 6' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:34:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:52:28', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '239b7c10-1575-409d-adc1-a36a31a0c563' | System           | 15 Sep 2020 21:53:12 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System           | 15 Sep 2020 21:53:12 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:34:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:52:39', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '239b7c10-1575-409d-adc1-a36a31a0c563' User entered '97.2' | System           | 15 Sep 2020 21:53:12 |
|                                                                                                                                                                                                                                                                | System           | 15 Sep 2020 21:53:12 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:52:42', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '239b7c10-1575-409d-adc1-a36a31a0c563' | System           | 15 Sep 2020 21:53:12 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 15 Sep 2020 21:53:12 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:05', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '239b7c10-1575-409d-adc1-a36a31a0c563' | System           | 15 Sep 2020 21:53:12 |
| User entered '15 Sep 2020 16:53'                                                                                                                                                                                                           | System           | 15 Sep 2020 21:53:12 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '15 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '16 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 7' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:34:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:23:15', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '05d7f59e-0994-4f3e-b3ba-2874ed93fa12' | System           | 17 Sep 2020 04:27:34 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System           | 17 Sep 2020 04:27:34 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:34:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:23:23', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '05d7f59e-0994-4f3e-b3ba-2874ed93fa12' | System           | 17 Sep 2020 04:27:34 |
| User entered '99.2'                                                                                                                                                                                                                        | System           | 17 Sep 2020 04:27:34 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:23:26', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '05d7f59e-0994-4f3e-b3ba-2874ed93fa12' | System           | 17 Sep 2020 04:27:34 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 17 Sep 2020 04:27:34 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:23:37', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '05d7f59e-0994-4f3e-b3ba-2874ed93fa12' | System           | 17 Sep 2020 04:27:34 |
| User entered '16 Sep 2020 23:23'                                                                                                                                                                                                           | System           | 17 Sep 2020 04:27:34 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '16 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '17 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                                                                | User             | Time (GMT)           |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.                                                   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:23:45', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'd32418ff-5a96-4ed2-88b0-560e1a86580a' | System           | 10 Sep 2020 23:24:28 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System           | 10 Sep 2020 23:24:28 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:02', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'd32418ff-5a96-4ed2-88b0-560e1a86580a' | System           | 10 Sep 2020 23:24:28 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 10 Sep 2020 23:24:28 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:05', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'd32418ff-5a96-4ed2-88b0-560e1a86580a' | System           | 10 Sep 2020 23:24:28 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 10 Sep 2020 23:24:28 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:20', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'd32418ff-5a96-4ed2-88b0-560e1a86580a' | System           | 10 Sep 2020 23:24:28 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System           | 10 Sep 2020 23:24:28 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:26', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'd32418ff-5a96-4ed2-88b0-560e1a86580a' | System           | 10 Sep 2020 23:24:28 |
| User entered '10 Sep 2020 18:24'                                                                                                                                                                                                           | System           | 10 Sep 2020 23:24:28 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '10 Sep 2020 18:06' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '10 Sep 2020 20:36' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                                             | User             | Time (GMT)           |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.                                | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 1, after vaccination (at home)' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | User                      | Time (GMT)                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|------------------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)          | 25 Feb 2021 15:24:07         |
| User closed query 'Per DM CLR: Per Diary Dose 1 Day 1 and 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness and Dose 1 Day 1 Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).                                                                                                                                                                                                                                                                  | (b) (4), (b) (6)          | 24 Feb 2021 16:19:41         |
| Query 'Per DM CLR: Per Diary Dose 1 Day 1 and 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness and Dose 1 Day 1 Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'when recording in the diary, pt selected this if medication was taken OR symptom interfered with some activity. according to the diary, the pt did NOT take any medication, rather this symptom interfered with some activity. there is no conmed to report.' (Site from DM). | Olivia Hapanowicz (b) (4) | (b) (4) 23 Feb 2021 17:07:01 |
| User opened query 'Per DM CLR: Per Diary Dose 1 Day 1 and 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness and Dose 1 Day 1 Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).                                                                                                                                                                                                                                                                  | (b) (4), (b) (6)          | 23 Feb 2021 07:25:52         |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

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 (d0db8a44b142a52b)', Time: '2020-09-11T03:54:49', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef' | System | 11 Sep 2020 08:59:54 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'                                                                                                                                   | System | 11 Sep 2020 08:59:54 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:55:38', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef' | System           | 11 Sep 2020 08:59:54 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 11 Sep 2020 08:59:54 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                                             | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                 | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:55:49', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef' User entered 'Yes (Y)' | System           | 11 Sep 2020 08:59:54 |
|                                                                                                                                                                                                                                                                   | System           | 11 Sep 2020 08:59:54 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

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

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

| Audit                                                                                                                                                                                                                                                        | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                            | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:58:19', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef' User entered '30' | System           | 11 Sep 2020 08:59:54 |
|                                                                                                                                                                                                                                                              | System           | 11 Sep 2020 08:59:54 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:59:23', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef' | System           | 11 Sep 2020 08:59:54 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'                                                                                                                              | System           | 11 Sep 2020 08:59:54 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:59:38', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '9b7c6403-2abc-4d74-9eda-e44e0ccf14ef' | System           | 11 Sep 2020 08:59:54 |
| User entered '11 Sep 2020 03:59'                                                                                                                                                                                                           | System           | 11 Sep 2020 08:59:54 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '10 Sep 2020 21:31' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '11 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 2' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:25:12', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8' | System           | 12 Sep 2020 09:30:40 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'                                                                                                                                   | System           | 12 Sep 2020 09:30:40 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:34:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:28:14', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8' | System           | 12 Sep 2020 09:30:40 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System           | 12 Sep 2020 09:30:40 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:34:57

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

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:29:39', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8' | System           | 12 Sep 2020 09:30:40 |
| User entered '30'                                                                                                                                                                                                                          | System           | 12 Sep 2020 09:30:40 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:29:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8' | System           | 12 Sep 2020 09:30:40 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System           | 12 Sep 2020 09:30:40 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:34:57

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

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:29:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8' | System           | 12 Sep 2020 09:30:40 |
| User entered '40'                                                                                                                                                                                                                          | System           | 12 Sep 2020 09:30:40 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:30:12', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8' | System           | 12 Sep 2020 09:30:40 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'                                                                                                                              | System           | 12 Sep 2020 09:30:40 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:30:35', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '69ac088f-df01-42ce-8a03-4d8a8b3fa1b8' | System           | 12 Sep 2020 09:30:40 |
| User entered '12 Sep 2020 04:30'                                                                                                                                                                                                           | System           | 12 Sep 2020 09:30:40 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '11 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '12 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 3' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:22:21', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '611a068c-a1b8-4543-9ad7-c42e1f81a4da' | System           | 13 Sep 2020 10:24:47 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'                                                                                                                                   | System           | 13 Sep 2020 10:24:47 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:34:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:22:25', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '611a068c-a1b8-4543-9ad7-c42e1f81a4da' | System           | 13 Sep 2020 10:24:47 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 13 Sep 2020 10:24:47 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:23:58', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '611a068c-a1b8-4543-9ad7-c42e1f81a4da' | System           | 13 Sep 2020 10:24:47 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 13 Sep 2020 10:24:47 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:25', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '611a068c-a1b8-4543-9ad7-c42e1f81a4da' | System           | 13 Sep 2020 10:24:47 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System           | 13 Sep 2020 10:24:47 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '611a068c-a1b8-4543-9ad7-c42e1f81a4da' | System           | 13 Sep 2020 10:24:47 |
| User entered '13 Sep 2020 05:24'                                                                                                                                                                                                           | System           | 13 Sep 2020 10:24:47 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '12 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '13 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 4' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:20', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '8b7dfec4-252e-4148-bbf2-24ae0a0d823d' | System           | 14 Sep 2020 07:12:37 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System           | 14 Sep 2020 07:12:37 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:34:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:22', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '8b7dfec4-252e-4148-bbf2-24ae0a0d823d' | System           | 14 Sep 2020 07:12:37 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 14 Sep 2020 07:12:37 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:25', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '8b7dfec4-252e-4148-bbf2-24ae0a0d823d' | System           | 14 Sep 2020 07:12:37 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 14 Sep 2020 07:12:37 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:29', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '8b7dfec4-252e-4148-bbf2-24ae0a0d823d' | System           | 14 Sep 2020 07:12:37 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System           | 14 Sep 2020 07:12:37 |

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Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:34', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '8b7dfec4-252e-4148-bbf2-24ae0a0d823d' | System           | 14 Sep 2020 07:12:37 |
| User entered '14 Sep 2020 02:12'                                                                                                                                                                                                           | System           | 14 Sep 2020 07:12:37 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '13 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '14 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 5' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:34:57

Is there any REDNESS AT INJECTION SITE?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

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Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:34:57

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
|                   |                  |                      |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:34:57

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

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Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:34:57

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
|                   |                  |                      |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
|                   |                  |                      |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
|                   |                  |                      |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '14 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '15 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 6' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:12', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68be3b62-5c8a-4d48-83ce-1341a13c8df2' | System           | 15 Sep 2020 21:53:33 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System           | 15 Sep 2020 21:53:33 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:34:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:15', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68be3b62-5c8a-4d48-83ce-1341a13c8df2' | System           | 15 Sep 2020 21:53:33 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 15 Sep 2020 21:53:33 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:17', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68be3b62-5c8a-4d48-83ce-1341a13c8df2' | System           | 15 Sep 2020 21:53:33 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 15 Sep 2020 21:53:33 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:20', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68be3b62-5c8a-4d48-83ce-1341a13c8df2' | System           | 15 Sep 2020 21:53:33 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System           | 15 Sep 2020 21:53:33 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:26', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '68be3b62-5c8a-4d48-83ce-1341a13c8df2' | System           | 15 Sep 2020 21:53:33 |
| User entered '15 Sep 2020 16:53'                                                                                                                                                                                                           | System           | 15 Sep 2020 21:53:33 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '15 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '16 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 7' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:23:57', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a46c739d-cd57-48e7-b4d6-8fc8f31a91e4' | System           | 17 Sep 2020 04:27:38 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System           | 17 Sep 2020 04:27:38 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:34:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:23:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a46c739d-cd57-48e7-b4d6-8fc8f31a91e4' | System           | 17 Sep 2020 04:27:38 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 17 Sep 2020 04:27:38 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:01', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a46c739d-cd57-48e7-b4d6-8fc8f31a91e4' | System           | 17 Sep 2020 04:27:38 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 17 Sep 2020 04:27:38 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:34:57

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:03', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a46c739d-cd57-48e7-b4d6-8fc8f31a91e4' | System           | 17 Sep 2020 04:27:38 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System           | 17 Sep 2020 04:27:38 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:07', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a46c739d-cd57-48e7-b4d6-8fc8f31a91e4' | System           | 17 Sep 2020 04:27:38 |
| User entered '16 Sep 2020 23:24'                                                                                                                                                                                                           | System           | 17 Sep 2020 04:27:38 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '16 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '17 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                                                                | User             | Time (GMT)           |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.                                                   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:33', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7' | System           | 10 Sep 2020 23:25:18 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 10 Sep 2020 23:25:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:39', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7' | System           | 10 Sep 2020 23:25:18 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System           | 10 Sep 2020 23:25:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7' | System           | 10 Sep 2020 23:25:18 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 10 Sep 2020 23:25:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:48', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7' | System           | 10 Sep 2020 23:25:18 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 10 Sep 2020 23:25:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:51', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7' | System           | 10 Sep 2020 23:25:18 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 10 Sep 2020 23:25:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:24:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7' | System           | 10 Sep 2020 23:25:18 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 10 Sep 2020 23:25:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:25:11', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7' | System           | 10 Sep 2020 23:25:18 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 10 Sep 2020 23:25:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-10T18:25:14', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '1104f8e4-4f3b-4c6e-ba66-7fa626aa24f7' | System           | 10 Sep 2020 23:25:18 |
| User entered '10 Sep 2020 18:25'                                                                                                                                                                                                           | System           | 10 Sep 2020 23:25:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '10 Sep 2020 18:06' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '10 Sep 2020 20:36' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                                             | User             | Time (GMT)           |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.                                | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 1, after vaccination (at home)' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T03:59:48', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7' | System           | 11 Sep 2020 09:01:09 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 11 Sep 2020 09:01:09 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:00:32', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7' | System           | 11 Sep 2020 09:01:09 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System           | 11 Sep 2020 09:01:09 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:00:37', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7' | System           | 11 Sep 2020 09:01:09 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 11 Sep 2020 09:01:09 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:00:42', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7' | System           | 11 Sep 2020 09:01:09 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 11 Sep 2020 09:01:09 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:00:45', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7' | System           | 11 Sep 2020 09:01:09 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 11 Sep 2020 09:01:09 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:00:48', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7' | System           | 11 Sep 2020 09:01:09 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 11 Sep 2020 09:01:09 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:00:56', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7' | System           | 11 Sep 2020 09:01:09 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 11 Sep 2020 09:01:09 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-11T04:01:04', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '5f263881-dbf7-45b7-9868-20f78a4ac1c7' | System           | 11 Sep 2020 09:01:09 |
| User entered '11 Sep 2020 04:01'                                                                                                                                                                                                           | System           | 11 Sep 2020 09:01:09 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '10 Sep 2020 21:31' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '11 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 2' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:30:53', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8' | System           | 12 Sep 2020 09:31:58 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 12 Sep 2020 09:31:58 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:02', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8' | System           | 12 Sep 2020 09:31:58 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System           | 12 Sep 2020 09:31:58 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:08', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8' | System           | 12 Sep 2020 09:31:58 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 12 Sep 2020 09:31:58 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:11', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8' | System           | 12 Sep 2020 09:31:58 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 12 Sep 2020 09:31:58 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:31', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8' | System           | 12 Sep 2020 09:31:58 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                  | System           | 12 Sep 2020 09:31:58 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:34', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8' | System           | 12 Sep 2020 09:31:58 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 12 Sep 2020 09:31:58 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:39', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8' | System           | 12 Sep 2020 09:31:58 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 12 Sep 2020 09:31:58 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-12T04:31:53', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '7118e608-5603-4a81-ad41-221f474b73d8' | System           | 12 Sep 2020 09:31:58 |
| User entered '12 Sep 2020 04:31'                                                                                                                                                                                                           | System           | 12 Sep 2020 09:31:58 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '11 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '12 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 3' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:47', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3' | System           | 13 Sep 2020 10:25:17 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 13 Sep 2020 10:25:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:51', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3' | System           | 13 Sep 2020 10:25:17 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 13 Sep 2020 10:25:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:54', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3' | System           | 13 Sep 2020 10:25:17 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 13 Sep 2020 10:25:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:57', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3' | System           | 13 Sep 2020 10:25:17 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 13 Sep 2020 10:25:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:24:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3' | System           | 13 Sep 2020 10:25:17 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 13 Sep 2020 10:25:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:25:02', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3' | System           | 13 Sep 2020 10:25:17 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 13 Sep 2020 10:25:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:25:05', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3' | System           | 13 Sep 2020 10:25:17 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 13 Sep 2020 10:25:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-13T05:25:14', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a149f420-7c3c-4ae5-a5d4-b91771a9d5a3' | System           | 13 Sep 2020 10:25:17 |
| User entered '13 Sep 2020 05:25'                                                                                                                                                                                                           | System           | 13 Sep 2020 10:25:17 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '12 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '13 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 4' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:40', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630' | System           | 14 Sep 2020 07:13:04 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 14 Sep 2020 07:13:04 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:42', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630' | System           | 14 Sep 2020 07:13:04 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 14 Sep 2020 07:13:04 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:45', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630' | System           | 14 Sep 2020 07:13:04 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 14 Sep 2020 07:13:04 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:47', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630' | System           | 14 Sep 2020 07:13:04 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 14 Sep 2020 07:13:04 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:49', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630' | System           | 14 Sep 2020 07:13:04 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 14 Sep 2020 07:13:04 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:51', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630' | System           | 14 Sep 2020 07:13:04 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 14 Sep 2020 07:13:04 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:54', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630' | System           | 14 Sep 2020 07:13:04 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 14 Sep 2020 07:13:04 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-14T02:12:59', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '644bc8af-af24-4cb9-ac7a-6c51f61ba630' | System           | 14 Sep 2020 07:13:04 |
| User entered '14 Sep 2020 02:12'                                                                                                                                                                                                           | System           | 14 Sep 2020 07:13:04 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '13 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '14 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 5' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
|                   |                  |                      |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
|                   |                  |                      |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
|                   |                  |                      |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '14 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '15 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 6' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:32', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401' | System           | 15 Sep 2020 21:54:03 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:38', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401' | System           | 15 Sep 2020 21:54:03 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:41', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401' | System           | 15 Sep 2020 21:54:03 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401' | System           | 15 Sep 2020 21:54:03 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:46', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401' | System           | 15 Sep 2020 21:54:03 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:48', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401' | System           | 15 Sep 2020 21:54:03 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:51', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401' | System           | 15 Sep 2020 21:54:03 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-15T16:53:55', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '684a3bf2-c7a0-4d08-8ec4-804c3239d401' | System           | 15 Sep 2020 21:54:03 |
| User entered '15 Sep 2020 16:53'                                                                                                                                                                                                           | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '15 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '16 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 7' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:20', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982' | System           | 17 Sep 2020 04:27:36 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 17 Sep 2020 04:27:36 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:34', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982' | System           | 17 Sep 2020 04:27:36 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System           | 17 Sep 2020 04:27:36 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:37', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982' | System           | 17 Sep 2020 04:27:36 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 17 Sep 2020 04:27:36 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:38', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982' | System           | 17 Sep 2020 04:27:36 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 17 Sep 2020 04:27:36 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:41', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982' | System           | 17 Sep 2020 04:27:36 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 17 Sep 2020 04:27:36 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:43', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982' | System           | 17 Sep 2020 04:27:36 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 17 Sep 2020 04:27:36 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:49', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982' | System           | 17 Sep 2020 04:27:36 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 17 Sep 2020 04:27:36 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-16T23:24:56', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '47eb2dd7-5bcc-4043-8727-d2d71c123982' | System           | 17 Sep 2020 04:27:36 |
| User entered '16 Sep 2020 23:24'                                                                                                                                                                                                           | System           | 17 Sep 2020 04:27:36 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '16 Sep 2020 12:00' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '17 Sep 2020 11:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 15 Sep 2020 21:54:03 |
| User entered 'Day 8' | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-17T23:21:56', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '956cb39d-9d48-4019-a15a-a54bd0c9ff8d' | System           | 18 Sep 2020 04:22:06 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System           | 18 Sep 2020 04:22:06 |

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:34:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-17T23:22:01', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: '956cb39d-9d48-4019-a15a-a54bd0c9ff8d' | System           | 18 Sep 2020 04:22:06 |
| User entered '17 Sep 2020 23:22'                                                                                                                                                                                                           | System           | 18 Sep 2020 04:22:06 |

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '17 Sep 2020 12:00' | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '18 Sep 2020 11:59' | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:34:57

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.   | System           | 15 Sep 2020 21:54:03 |
| User entered 'Day 8' | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-17T23:22:09', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'c5ddea70-a3e6-416a-acb1-a0e7a01af8fa' | System           | 18 Sep 2020 04:22:16 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 18 Sep 2020 04:22:16 |

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:34:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                       | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                           | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-09-17T23:22:14', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'c5ddea70-a3e6-416a-acb1-a0e7a01af8fa' User entered '17 Sep 2020 23:22' | System           | 18 Sep 2020 04:22:16 |
|                                                                                                                                                                                                                                                                             | System           | 18 Sep 2020 04:22:16 |

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:34:57

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '17 Sep 2020 12:00' | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:34:57

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| User entered '18 Sep 2020 11:59' | System           | 15 Sep 2020 21:54:03 |

US3342239

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:57

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 18 Sep 2020 21:35:45 |

US3342239

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:57

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '18 Sep 2020' | Ethan Shotton (b) (4) | 18 Sep 2020 21:35:45 |

US3342239

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.                  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Contact Made (CONTACT MADE)' | Ethan Shotton (b) (4) | 18 Sep 2020 21:35:45 |

US3342239

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Ethan Shotton (b) (4) | 18 Sep 2020 21:35:45 |

US3342239

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 18 Sep 2020 21:35:50 |

US3342239

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:34:57**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '1'  | System           | 18 Sep 2020 21:35:50 |

US3342239

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:57

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 24 Sep 2020 16:07:17 |

US3342239

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:57

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '24 Sep 2020' | Ethan Shotton (b) (4) | 24 Sep 2020 16:07:17 |

US3342239

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.                  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Contact Made (CONTACT MADE)' | Ethan Shotton (b) (4) | 24 Sep 2020 16:07:17 |

US3342239

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Ethan Shotton (b) (4) | 24 Sep 2020 16:07:17 |

US3342239

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:34:57**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 24 Sep 2020 16:07:21 |

US3342239

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:34:57**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '1'  | System           | 24 Sep 2020 16:07:21 |

US3342239

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:57

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 01 Oct 2020 18:39:41 |

US3342239

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '1 Oct 2020' | Ethan Shotton (b) (4) | 01 Oct 2020 18:39:41 |

US3342239

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded.                  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Contact Made (CONTACT MADE)' | Ethan Shotton (b) (4) | 01 Oct 2020 18:39:41 |

US3342239

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Ethan Shotton (b) (4) | 01 Oct 2020 18:39:41 |

US3342239

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:56:45 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 01 Oct 2020 18:39:45 |

US3342239

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:34:57**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:56:45 |
| User entered '1'  | System           | 01 Oct 2020 18:39:45 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:01:29 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered '13 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:01:29 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded.      | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:01:29 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered 'VISIT2' | System           | 13 Oct 2020 20:01:29 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Timepoint](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered '13 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered '14:27'      | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '13 Oct 2020 14:27' | System           | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered '98.0' F     | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered '75'         | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered 'bpm' | System           | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered '12'         | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered 'breaths/min' | System           | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered '102'        | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered 'mmHg' | System           | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered '63'         | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:34:57

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered 'mmHg' | System           | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Timepoint](#)

| Audit                                              | User             | Time (GMT)           |
|----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Were vital signs assessed?](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                      | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded.                                                              | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                |                      |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 14 Oct 2020 16:44:20 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Eileen Euperio (b) (4) | 14 Oct 2020 16:44:20 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                |                      |
| User entered empty.                                                                    | System                 | 13 Oct 2020 20:02:21 |
|                                                                                        | (b) (4), (b) (6)       | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Route of measurement](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:34:57

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 13 Oct 2020 20:02:21 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:57

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:26 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:57

Date of examination (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:26 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[Was study treatment given?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 14 Oct 2020 16:45:52 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[If No, reason not given](#)

| Audit                                                                    | User                   | Time (GMT)           |
|--------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                        | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded.                                                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)' | Eileen Euperio (b) (4) | 14 Oct 2020 16:45:52 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

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

| Audit                                                                                                                            | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                                                                | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded.                                                                                                        | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'subject had AE of head trauma following phlebotomy attempt. Blood and NP swabs not collected, IP not administered' | Eileen Euperio (b) (4) | 14 Oct 2020 16:45:52 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[What was the study treatment?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 14 Oct 2020 16:45:52 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:45:52 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:45:52 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[Treatment Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 14 Oct 2020 16:45:52 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[Which arm was used to give treatment?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:45:52 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 14 Oct 2020 16:45:52 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:34:57

[What was the route of administration for the study treatment?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 14 Oct 2020 16:45:52 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 14 Oct 2020 16:45:57 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

Collection date (dd MMM yyyy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:45:57 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

Collection time (00:00-23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:45:57 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 14 Oct 2020 16:45:57 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:34:57

Collection date (dd MMM yyyy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:02 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:57

[Lab Test](#)

| Audit                                                        | User                              | Time (GMT)           |
|--------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                            | (b) (4), (b) (6)                  | 28 Apr 2021 15:32:09 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Eileen Euperio (b) (4)<br>(b) (4) | 14 Oct 2020 16:46:02 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:57

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:02 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:57

Collection time (00:00 - 23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:02 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:34:57

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 14 Oct 2020 16:46:02 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:57

[Lab Test](#)

| Audit                                                        | User                              | Time (GMT)           |
|--------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                            | (b) (4), (b) (6)                  | 28 Apr 2021 15:32:09 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Eileen Euperio (b) (4)<br>(b) (4) | 14 Oct 2020 16:46:02 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:57

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:02 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:57

Collection time (00:00 - 23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:26 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:02 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:34:57

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 14 Oct 2020 16:46:02 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:18:26 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Oct 2020 20:02:29 |

US3342239

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '1'  | System           | 13 Oct 2020 20:02:29 |

US3342239

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:57

[Was Contact Attempted?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 19 Nov 2020 23:26:52 |

US3342239

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '23 Oct 2020' | Eileen Euperio (b) (4) | 19 Nov 2020 23:26:52 |

US3342239

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Please select one status for the follow-up contact](#)

| Audit                                              | User                   | Time (GMT)           |
|----------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded.                          | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | Eileen Euperio (b) (4) | 19 Nov 2020 23:26:52 |

US3342239

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                          | User                   | Time (GMT)           |
|------------------------------------------------|------------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)       | 28 Apr 2021 15:32:09 |
| User signature succeeded.                      | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '3X attempted calls unsuccessful' | Eileen Euperio (b) (4) | 19 Nov 2020 23:26:52 |

US3342239

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

[Is the participant continuing to the next visit?](#)

| Audit                                                     | User                    | Time (GMT)           |
|-----------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded.                                 | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)' reason for change: New Information | Darrell O'Brien (b) (4) | 23 Dec 2020 14:36:49 |
| User entered 'No (N)'                                     | Eileen Euperio (b) (4)  | 19 Nov 2020 23:26:59 |

US3342239

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:34:57**

[Continuing Flag](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '1'    | System           | 23 Dec 2020 14:36:49 |
| User entered empty. | System           | 19 Nov 2020 23:26:59 |

US3342239

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 23 Dec 2020 14:37:49 |

US3342239

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:57

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:37:49 |

US3342239

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Please select one status for the follow-up contact](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:37:49 |

US3342239

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:37:49 |

US3342239

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Darrell O'Brien (b) (4) | 23 Dec 2020 14:37:55 |

US3342239

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:34:57**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '1'  | System           | 23 Dec 2020 14:37:55 |

US3342239

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:34:57

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:04 |

US3342239

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:04 |

US3342239

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Please select one status for the follow-up contact](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:04 |

US3342239

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:34:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:04 |

US3342239

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:34:57**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:11 |

US3342239

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '1'  | System           | 23 Dec 2020 14:38:11 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Was this visit performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:21 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:21 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:21 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:34:57

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered 'VISIT3' | System           | 23 Dec 2020 14:38:21 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Were vital signs assessed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

Temperature (xxx.x)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Route of measurement](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:18:26 |
| User entered empty.       | (b) (4)<br>Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[If Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Pulse \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

Systolic Blood Pressure (xxx)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 23 Dec 2020 14:38:35 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
|                   |                  |                      |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:34:57

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
|                   |                  |                      |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:57

[Was the physical examination performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:41 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:34:57

Date of examination (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:41 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

[Was the sample collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:46 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

Collection date (dd MMM yyyy)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:46 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

Collection time (00:00-23:59)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered empty.       | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:46 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:34:57

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 23 Dec 2020 14:38:46 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:26 |
| User entered 'Yes (Y)'    | Darrell O'Brien (b) (4) | 23 Dec 2020 14:38:58 |

US3342239

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:34:57

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '1'  | System           | 23 Dec 2020 14:38:58 |

US3342239

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:34:57**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.    | System           | 10 Sep 2020 23:01:18 |
| User entered 'Day 64' | System           | 10 Sep 2020 23:01:18 |

US3342239

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:34:57**

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-11-13T16:27:30', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a6cb15ae-201a-4c59-9068-b9e9ddac03e5' | System           | 13 Nov 2020 22:27:47 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 13 Nov 2020 22:27:47 |

US3342239

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:34:57**

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

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-11-13T16:27:37', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a6cb15ae-201a-4c59-9068-b9e9ddac03e5' | System           | 13 Nov 2020 22:27:47 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System           | 13 Nov 2020 22:27:47 |

US3342239

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:34:57**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                          | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d0db8a44b142a52b)', Time: '2020-11-13T16:27:44', User OID: 'PatientReportedOutcome (US3342239)', ODM File OID: 'a6cb15ae-201a-4c59-9068-b9e9ddac03e5' | System           | 13 Nov 2020 22:27:47 |
| User entered '13 Nov 2020 16:27:44'                                                                                                                                                                                                        | System           | 13 Nov 2020 22:27:47 |

US3342239

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:34:57**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.               | System           | 10 Sep 2020 23:01:18 |
| User entered '10 Nov 2020 00:01' | System           | 10 Sep 2020 23:01:18 |

US3342239

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:34:57**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:24:07 |
| Data entry locked.               | System           | 10 Sep 2020 23:01:18 |
| User entered '14 Nov 2020 23:59' | System           | 10 Sep 2020 23:01:18 |

US3342239

**Folder:** Adverse Events

**Form:** Adverse Events Summary

**Generated On:** 11 Aug 2021 22:34:57

[Did the participant experience any adverse events?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:10 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:05 |
|                   |                  |                      |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Adverse event](#)

| Audit                                                                                                                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                                                                                                                            | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded.                                                                                                                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Head injury, LLT: Head injury - version MedDRA\\23.0. | Coder Import (b) (4)   | 14 Oct 2020 16:47:31 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                 | Coder Import (b) (4)   | 14 Oct 2020 16:47:31 |
| Data point term sent to Coder                                                                                                                                                                | System                 | 14 Oct 2020 16:47:02 |
| User entered 'head trauma'                                                                                                                                                                   | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Was this a medically-attended AE?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

Start date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '13 Oct 2020' | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Start time \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:05 |
| User entered empty. | System           | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Ongoing?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

If not Ongoing, end date (dd MMM yyyy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

End time (00:00-23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:05 |
| User entered empty. | System           | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Severity](#)

| Audit                                      | User                   | Time (GMT)           |
|--------------------------------------------|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded.                  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Is the adverse event serious?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Death](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Life threatening](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

Hospital Discharge Date (dd MMM yyyy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Admitted to ICU?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Number of Days in ICU](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 11 Aug 2021 22:34:57

[Persistent or significant disability or incapacity](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Congenital anomaly or birth defect](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Other medically important event](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Relationship to investigational product](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded.                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Not Related (NOT RELATED)' | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Relationship to Study Procedure](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded.        | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Related (RELATED)' | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

Action taken with investigational product

| Audit                                                                                                                                                                                                                                   | User                              | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                       | (b) (4), (b) (6)                  | 28 Apr 2021 15:32:05 |
| User signature succeeded.                                                                                                                                                                                                               | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User closed query 'Per CDM: Action taken is "Investigational Product Withdrawn" however no Dosing Discontinuation form has been added. Please review and clarify or update accordingly. ' (Site from DM).                               | (b) (4)<br>(b) (4), (b) (6)       | 20 Nov 2020 12:37:33 |
| Query 'Per CDM: Action taken is "Investigational Product Withdrawn" however no Dosing Discontinuation form has been added. Please review and clarify or update accordingly. ' answered with 'updated dosing disc. CRF' (Site from DM).  | Eileen Euperio (b) (4)<br>(b) (4) | 19 Nov 2020 23:25:07 |
| User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).             |                                   | 19 Nov 2020 23:24:39 |
| Query 'Action Taken with Investigational Product is System Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System). | System                            | 19 Nov 2020 23:24:39 |
| User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).                    | System                            | 11 Nov 2020 22:59:51 |
| User opened query 'Per CDM: Action taken is "Investigational Product Withdrawn" however no Dosing Discontinuation form has been added. Please review and clarify or update accordingly. ' (Site from DM).                               | (b) (4), (b) (6)                  | 22 Oct 2020 16:15:53 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)'                                                                                                                                                                            | Eileen Euperio (b) (4)<br>(b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[None](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '1'          | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Concomitant Medication](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Concomitant Procedure](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '0'          | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Outcome](#)

| Audit                                                      | User                   | Time (GMT)           |
|------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                          | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded.                                  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Narrative](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 15:32:05 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:05 |
| User entered '0'  | System           | 14 Oct 2020 16:46:41 |

US3342239

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:34:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:05 |
| User entered '1'  | System           | 14 Oct 2020 16:46:41 |

US3342239

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 11 Aug 2021 22:34:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:05 |
|                   |                  |                      |

US3342239

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

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

**Generated On: 11 Aug 2021 22:34:57**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Yes (Y)'    | Andrew Bell (b) (4)   | 10 Sep 2020 22:52:39 |

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:34:57

[Name of Medication](#)

| Audit                                                                                                                                                                             | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                                 | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.                                                                                                                                                         | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 10 Sep 2020 22:55:46 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                         | Coder Import (b) (4)  | 10 Sep 2020 22:55:46 |
| Data point term sent to Coder                                                                                                                                                     | System                | 10 Sep 2020 22:54:35 |
| User entered 'buspirone'                                                                                                                                                          | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Indication](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'anxiety'    | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '5'          | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Dose unit](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'mg (mg)'    | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[If dose unit is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Frequency](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.        | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'twice daily (BID)' | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Oral (ORAL)' | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[If route of administration is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'UN Jun 2018' | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '0'          | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'UN Feb 2019' | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Andrew Bell (b) (4)   | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '2'  | System           | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '1'  | System           | 10 Sep 2020 22:53:38 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:34:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '804 (804)' | System           | 10 Sep 2020 22:53:38 |

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:34:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                     | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                                                         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.                                                                                                                                                                                 | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 10 Sep 2020 22:55:46 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                 | Coder Import (b) (4)  | 10 Sep 2020 22:55:46 |
| Data point term sent to Coder                                                                                                                                                                             | System                | 10 Sep 2020 22:54:35 |
| User entered 'Gabapentin'                                                                                                                                                                                 | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Indication](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'anxiety'    | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '300'        | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Dose unit](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'mg (mg)'    | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[If dose unit is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Frequency](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.        | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'twice daily (BID)' | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Oral (ORAL)' | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[If route of administration is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'UN Jun 2018' | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '0'          | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'UN Feb 2019' | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Andrew Bell (b) (4)   | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '2'  | System           | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '1'  | System           | 10 Sep 2020 22:54:28 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:34:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '804 (804)' | System           | 10 Sep 2020 22:54:28 |

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:34:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                  | User                       | Time (GMT)                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------------------------------|
| Data hard locked.                                                                                                                                                                                                      | (b) (4), (b) (6)           | 28 Apr 2021 15:32:09                         |
| User signature succeeded.                                                                                                                                                                                              | Paul Pickrell (b) (4)      | 12 Mar 2021 23:18:15                         |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE HYDROCHLORIDE, PRODUCTSYNONYM: BUSPAR - version WHODrug-Global-B3\202003. | Coder Import (b) (4)       | 10 Sep 2020 22:55:46                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.                                                                                                               | Coder Import (b) (4)       | 10 Sep 2020 22:55:46                         |
| Data point term sent to Coder User entered 'buspar'                                                                                                                                                                    | System Andrew Bell (b) (4) | 10 Sep 2020 22:55:35<br>10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Indication](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'anxiety'    | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '30'         | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Dose unit](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'mg (mg)'    | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[If dose unit is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Frequency](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.        | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'twice daily (BID)' | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'Oral (ORAL)' | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[If route of administration is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered empty.       | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'UN Jan 2018' | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered '0'          | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'UN Jun 2018' | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Was this medication taken for solicited event?](#)

| Audit                                                                                  | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                      | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded.                                                              | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 10 Sep 2020 22:55:18 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 10 Sep 2020 22:55:18 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:18 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 10 Sep 2020 22:55:10 |
| User entered empty.                                                                    | System                | 10 Sep 2020 22:55:10 |
|                                                                                        | Andrew Bell (b) (4)   | 10 Sep 2020 22:55:10 |
|                                                                                        | (b) (4)               |                      |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '2'  | System           | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '1'  | System           | 10 Sep 2020 22:55:10 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:34:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered '804 (804)' | System           | 10 Sep 2020 22:55:10 |

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                 | User                                         | Time (GMT)                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|----------------------------------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6)                             | 28 Apr 2021 15:32:09                         |
| User signature succeeded.                                                                                                                                                                                                                                                             | Paul Pickrell (b) (4)                        | 12 Mar 2021 23:18:15                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: NAPROXEN -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4)   | 02 Oct 2020 19:43:49                         |
| 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)              | 02 Oct 2020 19:43:49                         |
| Data point term sent to Coder<br>User entered 'Naproxen'                                                                                                                                                                                                                              | System<br>Darrell O'Brien (b) (4)<br>(b) (4) | 02 Oct 2020 19:42:56<br>02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Indication](#)

| Audit                              | User                    | Time (GMT)           |
|------------------------------------|-------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded.          | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered 'Injection Site Pain' | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered '220'        | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered 'mg (mg)'    | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[If dose unit is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered empty.       | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded.      | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered 'as needed (PRN)' | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered empty.       | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered 'Oral (ORAL)' | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[If route of administration is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered empty.       | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered '11 Sep 2020' | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered '0'          | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 15:32:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)   | 12 Mar 2021 23:18:15 |
| User entered '12 Sep 2020' | Darrell O'Brien (b) (4) | 02 Oct 2020 19:42:26 |

US3342239

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:34:57

[Was this medication taken for solicited event?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | User                                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | (b) (4), (b) (6)                     | 28 Apr 2021 15:32:09 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Paul Pickrell (b) (4)                | 12 Mar 2021 23:18:15 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).                                                          | (b) (4)<br>(b) (4), (b) (6)          | 15 Jan 2021 17:21:15 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'Can confirm this did not meet AE reporting criteria.' (Site from DM). | Olivia Hapanowicz (b) (4)<br>(b) (4) | 14 Jan 2021 23:35:54 |



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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 02 Oct 2020 19:42:26 |

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 02 Oct 2020 19:42:26 |

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

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:34:57**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 15:32:09 |
| User entered empty. | System           | 02 Oct 2020 19:42:26 |

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:34:57**

[Were any concomitant procedures performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 15:32:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:18:15 |
| User entered 'No (N)'     | Ethan Shotton (b) (4) | 04 Mar 2021 23:21:32 |

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**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 22:34:57**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 27 Apr 2021 12:46:32 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '13 Oct 2020' reason for change: Data Entry Error | (b) (4)                |                      |
|                                                                | Eileen Euperio (b) (4) | 19 Nov 2020 23:24:39 |
| User entered '11 Nov 2020'                                     | (b) (4)                |                      |
|                                                                | Eileen Euperio (b) (4) | 11 Nov 2020 22:59:51 |
|                                                                | (b) (4)                |                      |

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:34:57

[Primary reason for dosing discontinuation](#)

| Audit                                                | User                   | Time (GMT)           |
|------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)       | 27 Apr 2021 12:46:32 |
| User signature succeeded.                            | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered 'AE (specify) (ADVERSE EVENT)'          | (b) (4)                | 19 Nov 2020 23:24:39 |
| reason for change: Data Entry Error                  | (b) (4)                |                      |
| User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)' | Eileen Euperio (b) (4) | 11 Nov 2020 22:59:51 |
|                                                      | (b) (4)                |                      |

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:34:57

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit                                                                                                                                                               | User                      | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                                                                                                                                   | (b) (4), (b) (6)          | 27 Apr 2021 12:46:32 |
| User signature succeeded.                                                                                                                                           | Paul Pickrell (b) (4)     | 12 Mar 2021 23:18:15 |
| User closed query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).             | (b) (4), (b) (6)          | 12 Mar 2021 10:32:56 |
| Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' answered with 'updated' (Site from DM). | Olivia Hapanowicz (b) (4) | 11 Mar 2021 20:54:52 |
| User entered 'AE #1' reason for change: Data Entry Error                                                                                                            | Olivia Hapanowicz (b) (4) | 11 Mar 2021 20:54:45 |
| User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).             | (b) (4), (b) (6)          | 02 Mar 2021 19:38:40 |
| User entered 'AE 1' reason for change: Data Entry Error                                                                                                             | Eileen Euperio (b) (4)    | 19 Nov 2020 23:24:39 |
| User entered empty.                                                                                                                                                 | Eileen Euperio (b) (4)    | 11 Nov 2020 22:59:51 |

US3342239

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:34:57**

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 27 Apr 2021 12:46:32 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered '11 Nov 2020' | Eileen Euperio (b) (4) | 11 Nov 2020 23:00:12 |

US3342239

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:34:57

[Reason for discontinuation](#)

| Audit                                                                                                                                                                                              | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                  | (b) (4), (b) (6)                  | 27 Apr 2021 12:46:32 |
| User signature succeeded.                                                                                                                                                                          | Paul Pickrell (b) (4)             | 12 Mar 2021 23:18:15 |
| User closed query 'Per CDM: If confirmed that subject was lost to follow up on 11Nov2020, please consider entering 'Safety Call Day 36 form, or comment accordingly. ' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)       | 20 Nov 2020 12:45:18 |
| Query 'Per CDM: If confirmed that subject was lost to follow up on 11Nov2020, please consider entering 'Safety Call Day 36 form, or comment accordingly. ' answered with 'updated' (Site from DM). | Eileen Euperio (b) (4)<br>(b) (4) | 19 Nov 2020 23:27:11 |
| User opened query 'Per CDM: If confirmed that subject was lost to follow up on 11Nov2020, please consider entering 'Safety Call Day 36 form, or comment accordingly. ' (Site from DM).             | (b) (4), (b) (6)                  | 18 Nov 2020 18:59:18 |
| User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'                                                                                                                                               | Eileen Euperio (b) (4)<br>(b) (4) | 11 Nov 2020 23:00:12 |

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**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:34:57**

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:46:32 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 11 Nov 2020 23:00:12 |

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**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:34:57**

[If reason for discontinuation is Death, main cause of death](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:46:32 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 11 Nov 2020 23:00:12 |

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**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:34:57**

[If main cause of death is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:46:32 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 11 Nov 2020 23:00:12 |

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**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:34:57**

[Date of death \(dd MMM yyyy\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:46:32 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 11 Nov 2020 23:00:12 |

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**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:34:57**

[Was autopsy performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:46:32 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:18:15 |
| User entered empty.       | Eileen Euperio (b) (4) | 11 Nov 2020 23:00:12 |