

US3292324 (Prod: Clinical Trials of Texas, Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:53:07

All time stamps listed in this document are displayed in GMT

US3292324

Form: Participant Creation

Generated On: 26 Nov 2020 10:53:07

[Participant ID](#)

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

US3292324

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 27 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> |
| | 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

Generated On: 26 Nov 2020 10:53:07

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:53:07

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Condition | TOTAL LEFT KNEE REPLACEMENT |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | JAN 2000 |
| Stop Year (derived) | 2000 |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Condition | HYSTERECTOMY |
| Start date (dd MMM yyyy) | UN UNK 2005 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2005 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2005 |
| Start Year (derived) | 2005 |
| Stop Month and Year (derived) | JAN 2005 |
| Stop Year (derived) | 2005 |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Condition | GASTRIC BYPASS SURGERY |
| Start date (dd MMM yyyy) | UN UNK 2008 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2008 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2008 |
| Start Year (derived) | 2008 |
| Stop Month and Year (derived) | JAN 2008 |
| Stop Year (derived) | 2008 |

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Condition | OBESITY |
| Start date (dd MMM yyyy) | |
| Start date completely unknown | True |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2008 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | |
| Start Year (derived) | |
| Stop Month and Year (derived) | JAN 2008 |
| Stop Year (derived) | 2008 |

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Condition | TYPE II DIABETES |
| Start date (dd MMM yyyy) | UN UNK 1999 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> 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 1999 |
| Start Year (derived) | 1999 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Condition | BILATERAL BREAST DUCTAL CARCINOMA IN SITU |
| Start date (dd MMM yyyy) | UN UNK 2014 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2014 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2014 |
| Start Year (derived) | 2014 |
| Stop Month and Year (derived) | JAN 2014 |
| Stop Year (derived) | 2014 |

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Condition | UTERINE FIBROIDS |
| Start date (dd MMM yyyy) | UN UNK 2005 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2005 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2005 |
| Start Year (derived) | 2005 |
| Stop Month and Year (derived) | JAN 2005 |
| Stop Year (derived) | 2005 |

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Condition | OSTEOARTHRITIS BILATERAL KNEES |
| Start date (dd MMM yyyy) | UN UNK 1973 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> 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 1973 |
| Start Year (derived) | 1973 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 27 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 08:44 (24 HR) |
| Vital Signs Date and Time (derived) | 27 AUG 2020 08:44 |
| Height (<i>xxx.x</i>) | 163.0 cm |
| Weight (<i>xxx.x</i>) | 93.5 kg |
| BMI (<i>xxx.x</i>) | 35.19139 kg/m ² |
| 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 checked="" type="radio"/> |
| If Other, specify | ND - Not Done |
| 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

Generated On: 26 Nov 2020 10:53:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:07

| | |
|--|---|
| Date of assessment (<i>dd MMM yyyy</i>) | 27 AUG 2020 |
| Is the participant of childbearing potential? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If No, what is the reason? | Surgically sterile <input checked="" type="radio"/> |
| | Post-menopausal <input type="radio"/> |
| | Partner medically sterile <input type="radio"/> |
| | Not reached age of Menarche <input type="radio"/> |
| | Other <input type="radio"/> |
| If Partner medically sterile or Other, specify _____ | |
| If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) | UN UNK 2005 |
| Date of surgery unknown | False |
| If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>) _____ | |
| Date of last menstruation unknown | False |

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 27 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:07

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

What was the participant's randomization number? 188281

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:07

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| 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) | 27 AUG 2020 |
| Time of assessment (00:00-23:59) | 09:25 (24 HR) |
| Vital Signs Date and Time (derived) | 27 AUG 2020 09:25 |
| Temperature (xxx.x) | 036.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 065 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 016 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 131 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 081 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 27 AUG 2020 |
| Time of assessment (00:00-23:59) | 11:00 (24 HR) |
| Vital Signs Date and Time (derived) | 27 AUG 2020 11:00 |
| Temperature (xxx.x) | 036.7 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 066 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 012 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 120 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 076 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:07

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

Generated On: 26 Nov 2020 10:53:07

| | |
|--|--|
| Was study treatment given? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, reason not given | Participant declined due to Adverse Event <input type="radio"/> |
| | Physician withheld dose due to Adverse Event <input type="radio"/> |
| | Death <input type="radio"/> |
| | Lost To Follow-Up <input type="radio"/> |
| | Physician Decision <input type="radio"/> |
| | Pregnancy <input type="radio"/> |
| | Protocol Deviation <input type="radio"/> |
| | Study Terminated by Sponsor <input type="radio"/> |
| | Withdrawal of Consent by Participant <input type="radio"/> |
| | Confirmed COVID-19 <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify | |
| What was the study treatment? | MRNA-1273 OR PLACEBO |
| What was the treatment date? (dd MMM yyyy) | 27 AUG 2020 |
| What was the treatment time? (00:00-23:59) | 10:30 (24 HR) |
| Treatment Date and Time (derived) | 27 AUG 2020 10:30 |
| Which arm was used to give treatment? | Left Arm <input checked="" type="radio"/> |
| | Right Arm <input type="radio"/> |
| What was the frequency of the study treatment dosing? | ONCE |
| What was the route of administration for the study treatment? | INTRAMUSCULAR |

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 27 AUG 2020 |
| Collection time (<i>00:00-23:59</i>) | 09:36 (24 HR) |
| Collection date and time (derived) | 27 AUG 2020 09:36 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:53:07

| | | | |
|--|---------------------------|--|------------------------------------|
| Collection date (<i>dd MMM yyyy</i>) | | | 27 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (<i>00:00 - 23:59</i>) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 09:47 | 27 AUG 2020 09:47 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 27 AUG 2020 11:03

PC Open Date & Time 27 AUG 2020 10:50

PC Close Date & Time 27 AUG 2020 13:20

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

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 98.8 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 27 AUG 2020 19:29 |
| PC Open Date & Time | 27 AUG 2020 14:15 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 18:52

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 07:41

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 19:58

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 20:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 20:54

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 19:46

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 11:04

PC Open Date & Time

27 AUG 2020 10:50

PC Close Date & Time

27 AUG 2020 13:20

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 19:30

PC Open Date & Time

27 AUG 2020 14:15

PC Close Date & Time

28 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 18:53

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

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

30 AUG 2020 07:41

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

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

30 AUG 2020 19:59

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 20:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 20:55

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 19:46

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

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 ☐

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 27 AUG 2020 11:04 |
| PC Open Date & Time | 27 AUG 2020 10:50 |
| PC Close Date & Time | 27 AUG 2020 13:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

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 ☐

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 27 AUG 2020 19:30 |
| PC Open Date & Time | 27 AUG 2020 14:15 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 AUG 2020 18:54 |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 AUG 2020 07:42 |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 AUG 2020 19:59 |
| PC Open Date & Time | 30 AUG 2020 12:00 |
| PC Close Date & Time | 31 AUG 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 31 AUG 2020 20:10 |
| PC Open Date & Time | 31 AUG 2020 12:00 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 01 SEP 2020 20:57 |
| PC Open Date & Time | 01 SEP 2020 12:00 |
| PC Close Date & Time | 02 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 SEP 2020 19:47 |
| PC Open Date & Time | 02 SEP 2020 12:00 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

Was Contact Attempted?

Yes ☒

No ☐

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

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292324

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

Was Contact Attempted?

Yes ☒

No ☐

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

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

ATTEMPTS WERE MADE, BUT
STAFF UNABLE TO CONTACT
PATIENT

If Contact Not Made, please provide Comments

US3292324

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 24 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

| | |
|-------------------------------------|---|
| 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) | 24 SEP 2020 |
| Time of assessment (00:00-23:59) | 09:15 (24 HR) |
| Vital Signs Date and Time (derived) | 24 SEP 2020 09:15 |
| Temperature (xxx.x) | 36.9 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 115 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 64 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

| | |
|-------------------------------------|--|
| Timepoint | Pre-Dose <input type="radio"/> |
| | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 24 SEP 2020 |
| Time of assessment (00:00-23:59) | 10:29 (24 HR) |
| Vital Signs Date and Time (derived) | 24 SEP 2020 10:29 |
| Temperature (xxx.x) | 36.6 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 68 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 117 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 74 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

| | |
|--|--|
| Was study treatment given? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, reason not given | Participant declined due to Adverse Event <input type="radio"/> |
| | Physician withheld dose due to Adverse Event <input type="radio"/> |
| | Death <input type="radio"/> |
| | Lost To Follow-Up <input type="radio"/> |
| | Physician Decision <input type="radio"/> |
| | Pregnancy <input type="radio"/> |
| | Protocol Deviation <input type="radio"/> |
| | Study Terminated by Sponsor <input type="radio"/> |
| | Withdrawal of Consent by Participant <input type="radio"/> |
| | Confirmed COVID-19 <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify | |
| What was the study treatment? | MRNA-1273 OR PLACEBO |
| What was the treatment date? (dd MMM yyyy) | 24 SEP 2020 |
| What was the treatment time? (00:00-23:59) | 09:59 (24 HR) |
| Treatment Date and Time (derived) | 24 SEP 2020 09:59 |
| Which arm was used to give treatment? | Left Arm <input checked="" type="radio"/> |
| | Right Arm <input type="radio"/> |
| What was the frequency of the study treatment dosing? | ONCE |
| What was the route of administration for the study treatment? | INTRAMUSCULAR |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 24 SEP 2020 |
| Collection time (<i>00:00-23:59</i>) | 09:22 (24 HR) |
| Collection date and time (derived) | 24 SEP 2020 09:22 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:53:07

| Collection date (dd MMM yyyy) | | | 24 SEP 2020 |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 09:40 | 24 SEP 2020 09:40 |
| Nasopharyngeal Swab 2 | No | | |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 10:32

PC Open Date & Time

24 SEP 2020 10:19

PC Close Date & Time

24 SEP 2020 12:49

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 24 SEP 2020 19:49 |
| PC Open Date & Time | 24 SEP 2020 13:44 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 99.6 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 25 SEP 2020 18:32 |
| PC Open Date & Time | 25 SEP 2020 12:00 |
| PC Close Date & Time | 26 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 11:06

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:12

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

28 SEP 2020 18:59

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 07:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 07:02

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

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

24 SEP 2020 10:32

PC Open Date & Time

24 SEP 2020 10:19

PC Close Date & Time

24 SEP 2020 12:49

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 19:49

PC Open Date & Time

24 SEP 2020 13:44

PC Close Date & Time

25 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 18:32

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

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

27 SEP 2020 11:07

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

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

27 SEP 2020 20:12

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 19:00

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

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

30 SEP 2020 07:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 07:02

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

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 ☐

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 24 SEP 2020 10:32 |
| PC Open Date & Time | 24 SEP 2020 10:19 |
| PC Close Date & Time | 24 SEP 2020 12:49 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

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 ☐

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 24 SEP 2020 19:49 |
| PC Open Date & Time | 24 SEP 2020 13:44 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 SEP 2020 18:34 |
| PC Open Date & Time | 25 SEP 2020 12:00 |
| PC Close Date & Time | 26 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 27 SEP 2020 11:07 |
| PC Open Date & Time | 26 SEP 2020 12:00 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 27 SEP 2020 20:13 |
| PC Open Date & Time | 27 SEP 2020 12:00 |
| PC Close Date & Time | 28 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 SEP 2020 19:00 |
| PC Open Date & Time | 28 SEP 2020 12:00 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 SEP 2020 07:02 |
| PC Open Date & Time | 29 SEP 2020 12:00 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

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 ☒

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 01 OCT 2020 07:02 |
| PC Open Date & Time | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

Was Contact Attempted?

Yes ☒

No ☐

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

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292324

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

Was Contact Attempted?

Yes ☒

No ☐

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

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292324

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 22 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 22 OCT 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 09:12 (24 HR) |
| Vital Signs Date and Time (derived) | 22 OCT 2020 09:12 |
| Temperature (<i>xxx.x</i>) | 37.1 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 75 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 123 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:07

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.

US3292324

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 22 OCT 2020 |
| Collection time (<i>00:00-23:59</i>) | 09:22 (24 HR) |
| Collection date and time (derived) | 22 OCT 2020 09:22 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 07:43:45

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 71 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 04 NOV 2020 19:53:42 |
| Patient Cloud Open Date & Time | 03 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 07 NOV 2020 23:59 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 78 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 11 NOV 2020 12:04:48 |
| Patient Cloud Open Date & Time | 10 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 14 NOV 2020 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 61 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 24 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 28 OCT 2020 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 68 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 75 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 07 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 11 NOV 2020 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 82 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 14 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 18 NOV 2020 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 03:28:42

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 96 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 103 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 05 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 09 DEC 2020 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 110 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 12 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 16 DEC 2020 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 117 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 19 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 23 DEC 2020 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 124 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 26 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 30 DEC 2020 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 131 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 138 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 145 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 16 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 20 JAN 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 152

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 159 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 166 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 06 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 10 FEB 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 173 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 180 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 187

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 13 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 17 MAR 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 03 APR 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 07 APR 2021 23:59 |
|---|-------------------|

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 10 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 14 APR 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 17 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 21 APR 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 24 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 28 APR 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 15 MAY 2021 00:01 |
| Patient Cloud Close Date & Time | 19 MAY 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 19 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 23 JUN 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 26 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 30 JUN 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 10 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 14 JUL 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 17 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 21 JUL 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 14 AUG 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 18 AUG 2021 23:59 |
|---|-------------------|

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 21 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 25 AUG 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 04 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 08 SEP 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 383 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 18 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 22 SEP 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 25 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 29 SEP 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 09 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 13 OCT 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 425 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 23 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 27 OCT 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 432 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 13 NOV 2021 00:01 |
| Patient Cloud Close Date & Time | 17 NOV 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 20 NOV 2021 00:01 |
| Patient Cloud Close Date & Time | 24 NOV 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 27 NOV 2021 00:01 |
| Patient Cloud Close Date & Time | 01 DEC 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 04 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 08 DEC 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 11 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 15 DEC 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 18 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 22 DEC 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 25 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 29 DEC 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 01 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 05 JAN 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 26 JAN 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 530

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 05 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 09 FEB 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 12 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 16 FEB 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|-----------------------------|--|
| Date and time of submission | |
|-----------------------------|--|

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 12 MAR 2022 00:01 |
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|---|-------------------|
| Patient Cloud Close Date & Time | 16 MAR 2022 23:59 |
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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 600 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 16 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 20 APR 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 23 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 27 APR 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 614 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 670 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 25 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 29 JUN 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| Date and time of submission | |
| Patient Cloud Open Date & Time | 02 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 06 JUL 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 09 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 13 JUL 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 691 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 16 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 20 JUL 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 23 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 27 JUL 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 13 AUG 2022 00:01 |
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|---|-------------------|
| Patient Cloud Close Date & Time | 17 AUG 2022 23:59 |
|---|-------------------|

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 726 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 20 AUG 2022 00:01 |
| Patient Cloud Close Date & Time | 24 AUG 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 747 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 10 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 14 SEP 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 754 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 761 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 01 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 05 OCT 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 775 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 08 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 12 OCT 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 26 OCT 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

| TIMEPOINT | DAY 796 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3292324

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

Was Contact Attempted?

Yes ☒

No ☐

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

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292324

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292324

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:53:07

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

US3292324

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:53:07

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3292324

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:53:07

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

| | |
|--|--|
| AEID | |
| Adverse event | URINARY TRACT INFECTION |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 16 SEP 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 26 SEP 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| v6.020 DTW (1102) | 349 of 1834 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

| | |
|--|---|
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> 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"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

| | |
|--|--|
| AEID | USA-US072-2020-MRNA-1273-P30 1000008 |
| Adverse event | R BROKEN FEMUR |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 3 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 3 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |
| v6.020 DTW (1102) | 351 of 1834 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | False |
| Concomitant Procedure | True |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

SUBJECT CALLED TO INFORM
US SHE IS CURRENTLY
ADMITTED AT METROPOLITAN
METHODIST FOR A BROKEN
FEMUR. SHE STATES SHE
BROKE HER FEMUR
YESTERDAY(03-NOV-2020)
DURING A FALL PICKING UP
HER GROCERIES. SHE WENT TO
THE ER (AT HOSPITAL STATED
ABOVE) AND WAS TAKEN TO
THE OR FOR SURGERY FOR
REPAIR. SHE IS CURRENTLY
STAYING FOR OBSERVATION
AND IS EXPECTED TO STAY
FOR ABOUT 3-4 DAYS.
RECORDS WILL BE
REQUESTED.

| | |
|--|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | 0 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:53:07

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

| | |
|--------------------------------|--|
| Name of Medication | CENTRUM SILVER |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | NUTRITIONAL SUPPLEMENT |
| Dose per administration | 1 |
| Dose unit | mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

| | | |
|--|--------------------------|----------------------------------|
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 2010 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

| | |
|--------------------------------|--|
| Name of Medication | B12 |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | NUTRITIONAL SUPPLEMENT |
| Dose per administration | 1 |
| Dose unit | mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

| | |
|--|--------------------------------------|
| Respiratory (Inhalation) | <input type="checkbox"/> |
| Intralesional | <input type="checkbox"/> |
| Intraperitoneal | <input type="checkbox"/> |
| Nasal | <input type="checkbox"/> |
| Vaginal | <input type="checkbox"/> |
| Rectal | <input type="checkbox"/> |
| Intravenous | <input type="checkbox"/> |
| Intravenous Bolus | <input type="checkbox"/> |
| Intravenous Drip | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | |
| Start date (dd MMM yyyy) | UN UNK 2015 |
| Start date completely unknown | False |
| Ongoing? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | |
| Was this medication taken for solicited event? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 <input type="radio"/> |
| | 803 <input type="radio"/> |
| | 804 <input checked="" type="radio"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

| | |
|--------------------------------------|--|
| Name of Medication | BIOTIN |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | NUTRITIONAL SUPPLEMENT |
| Dose per administration | 5000 |
| Dose unit | mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

| | | |
|---|--------------------------|----------------------------------|
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| <hr/> | | |
| If route of administration is Other, specify <input type="text"/> | | |
| <hr/> | | |
| Start date (dd MMM yyyy) | 20 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| <hr/> | | |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/> | | |
| <hr/> | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| <hr/> | | |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

| | |
|--------------------------------------|--|
| Name of Medication | SYNTHROID |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | THYROID CANCER |
| Dose per administration | 200 |
| Dose unit | mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

| | | |
|--|--------------------------|----------------------------------|
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2014 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

| | |
|--------------------------------------|--|
| Name of Medication | TYLENOL |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | FEVER/PAIN |
| Dose per administration | 500 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

| | |
|--|---|
| Respiratory (Inhalation) | <input type="checkbox"/> |
| Intralesional | <input type="checkbox"/> |
| Intraperitoneal | <input type="checkbox"/> |
| Nasal | <input type="checkbox"/> |
| Vaginal | <input type="checkbox"/> |
| Rectal | <input type="checkbox"/> |
| Intravenous | <input type="checkbox"/> |
| Intravenous Bolus | <input type="checkbox"/> |
| Intravenous Drip | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | |
| Start date (dd MMM yyyy) | 25 SEP 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 25 SEP 2020 | |
| Was this medication taken for solicited event? | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Separate Dosage Number (derived) | 1 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

| | |
|--------------------------------|---|
| Name of Medication | SULFAMETHOXAZOLE |
| Prophylaxis | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| Indication | URINARY TRACT INFECTION |
| Dose per administration | UNK |
| Dose unit | mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/> |
| If dose unit is Other, specify | SUBJECT BOTTLE DOES NOT STATE DOSE |
| Frequency | once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

| | | |
|--|--------------------------|----------------------------------|
| | 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) | | 16 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) 26 SEP 2020 | | |
| 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"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

| | |
|--------------------------------|--|
| Name of Medication | ACYCLOVIR |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | SHINGLES |
| Dose per administration | 400 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify | |
| Frequency | once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

| | |
|--|---|
| Respiratory (Inhalation) | <input type="checkbox"/> |
| Intralesional | <input type="checkbox"/> |
| Intraperitoneal | <input type="checkbox"/> |
| Nasal | <input type="checkbox"/> |
| Vaginal | <input type="checkbox"/> |
| Rectal | <input type="checkbox"/> |
| Intravenous | <input type="checkbox"/> |
| Intravenous Bolus | <input type="checkbox"/> |
| Intravenous Drip | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | |
| Start date (dd MMM yyyy) | 14 SEP 2020 |
| Start date completely unknown | False |
| Ongoing? | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 24 SEP 2020 |
| Was this medication taken for solicited event? | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 2 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/> |

US3292324

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:53:07

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3292324

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:53:07

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3292324

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:53:07

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

| | |
|--|---|
| SAEID | USA-US072-2020-MRNA-1273-P301000008 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 1 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:53:07

| | |
|---|--|
| SAEID | USA-US072-2020-MRNA-1273-P301000008 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | DOUGLAS |
| Investigator's Last Name | DENHAM |
| Site Address: Street | 7940 FLOYD CURL DRIVE |
| Site Address: City | SAN ANTONIO |
| Site Address: State | |
| Site Address: Postal Code | 78229 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 1 |
| Date of submission (Pre-filled from custom function) | 04/NOV/2020 18:49 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3292324 (Prod: Clinical Trials of Texas, Inc)

US3292324

Form: Participant Creation

Generated On: 26 Nov 2020 10:53:07

[Participant ID](#)

| Audit | User | Time (GMT) |
|--------------------------|---|----------------------|
| User entered 'US3292324' | RWS_ENDPOINT ENDPOINT (b) (4) <div></div> | 27 Aug 2020 14:14:42 |

US3292324

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 12:38:44 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User entered '27 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 27 Aug 2020 14:14:43 |

US3292324

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 28 Aug 2020 12:38:44 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 28 Aug 2020 12:38:44 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User entered (b) (6) 1954' | RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 27 Aug 2020 14:14:44 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[Age](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '66' | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 28 Aug 2020 12:39:06 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '66' | System | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| User entered 'Female (F)' | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

White

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered 'I' | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[Black](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[Asian](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[Other](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[Unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:07

[Not reported](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:39:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:07

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '27 Aug 2020' | Nathan Cortez (b) (4) [REDACTED] | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2020' | System | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:07

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| User entered 'Amendment 3 (3)' | Nathan Cortez (b) (4) [REDACTED] | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) [REDACTED] | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:07

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:07

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Nathan Cortez (b) (4) [REDACTED] | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:07

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------|--|----------------------|
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 27 Aug 2020 14:14:43 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:07

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 27 Aug 2020 15:42:56 |

US3292324

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:53:07

Did the participant meet all eligibility criteria?

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 27 Aug 2020 15:42:56 |

US3292324

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:53:07

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 12:39:11 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:07

Condition

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 31 Aug 2020 15:26:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 31 Aug 2020 15:26:36 |
| Data point term sent to Coder | System | 28 Aug 2020 12:48:35 |
| User entered 'fenofibrate allergy' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2010' | (b) (4), (b) (6) | 28 Aug 2020 12:47:43 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:47:43 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 12:47:43 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:07

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 12:47:43 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:47:43 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2010' | System | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:49:49 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:49:49 |
| Data point term sent to Coder | System | 28 Aug 2020 12:48:37 |
| User entered 'total left knee replacement' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 12:48:15 |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2000' | (b) (4), (b) (6) | 28 Aug 2020 12:48:15 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:48:15 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 12:48:15 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:07

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2000' | (b) (4), (b) (6) | 28 Aug 2020 12:48:15 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:48:15 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 28 Aug 2020 12:48:15 |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2000' | System | 28 Aug 2020 12:48:15 |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 28 Aug 2020 12:48:15 |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2000' | System | 28 Aug 2020 12:48:15 |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 15 Oct 2020 21:52:12 |
| Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 24 Sep 2020 01:03:56 |
| User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 09 Sep 2020 19:19:43 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone operation, LLT: Bone operation - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 29 Aug 2020 07:56:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 29 Aug 2020 07:56:37 |
| Data point term sent to Coder | System | 28 Aug 2020 12:49:40 |
| User entered 'left femur reconstruction' | (b) (4), (b) (6) | 28 Aug 2020 12:48:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2015' | (b) (4), (b) (6) | 28 Aug 2020 12:48:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:48:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 12:48:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:07

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2015' | (b) (4), (b) (6) | 28 Aug 2020 12:48:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:48:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2015' | System | 28 Aug 2020 12:48:40 |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2015' | System | 28 Aug 2020 12:48:40 |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2015' | System | 28 Aug 2020 12:48:40 |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2015' | System | 28 Aug 2020 12:48:40 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Mastectomy, LLT: Mastectomy bilateral - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 29 Aug 2020 07:45:31 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 29 Aug 2020 07:45:31 |
| Data point term sent to Coder | System | 28 Aug 2020 12:49:40 |
| User entered 'mastectomy - bilateral' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2014' | (b) (4), (b) (6) | 28 Aug 2020 12:49:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:49:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 12:49:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2014' | (b) (4), (b) (6) | 28 Aug 2020 12:49:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:49:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2014' | System | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2014' | System | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:50:36 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:50:36 |
| Data point term sent to Coder | System | 28 Aug 2020 12:49:41 |
| User entered 'thyroidectomy' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2014' | (b) (4), (b) (6) | 28 Aug 2020 12:49:31 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:49:31 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 12:49:31 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2014' | (b) (4), (b) (6) | 28 Aug 2020 12:49:31 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:49:31 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2014' | System | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2014' | System | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:51:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:51:41 |
| Data point term sent to Coder | System | 28 Aug 2020 12:50:42 |
| User entered 'hysterectomy' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2005' | (b) (4), (b) (6) | 28 Aug 2020 12:49:45 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:49:45 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 12:49:45 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:07

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2005' | (b) (4), (b) (6) | 28 Aug 2020 12:49:45 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:49:45 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2005' | System | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2005' | System | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:51:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:51:41 |
| Data point term sent to Coder | System | 28 Aug 2020 12:50:43 |
| User entered 'cholecystectomy' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2017' | (b) (4), (b) (6) | 28 Aug 2020 12:50:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:50:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 12:50:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:07

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2017' | (b) (4), (b) (6) | 28 Aug 2020 12:50:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:50:06 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2017' | System | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2017' | System | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:51:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:51:41 |
| Data point term sent to Coder | System | 28 Aug 2020 12:50:43 |
| User entered 'gastric bypass surgery' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2008' | (b) (4), (b) (6) | 28 Aug 2020 12:50:27 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:50:27 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 12:50:27 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:07

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2008' | (b) (4), (b) (6) | 28 Aug 2020 12:50:27 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:50:27 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2008' | System | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2008' | System | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2008' | System | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2008' | System | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 15:10:10 |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 24 Sep 2020 01:04:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 24 Sep 2020 01:04:40 |
| Data point term sent to Coder | System | 24 Sep 2020 01:04:26 |
| Query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 24 Sep 2020 01:04:18 |
| Coding entries removed. | Dawn Killian (b) (4) (b) (4) | 24 Sep 2020 01:04:11 |
| User entered 'bilateral DECREASED VISUAL ACUITY' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 24 Sep 2020 01:04:11 |
| User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 09 Sep 2020 19:20:36 |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:51:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:51:41 |
| Data point term sent to Coder | System | 28 Aug 2020 12:50:43 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'decreased visual acuity' | (b) (4), (b) (6) | 28 Aug 2020 12:50:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2010' | (b) (4), (b) (6) | 28 Aug 2020 12:50:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:50:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 12:50:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 12:50:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:50:40 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 28 Aug 2020 12:50:40 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2010' | System | 28 Aug 2020 12:50:40 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Aug 2020 12:50:40 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Aug 2020 12:50:40 |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 12:54:37 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 12:54:37 |
| Data point term sent to Coder | System | 28 Aug 2020 12:53:47 |
| User entered 'cholelithiasis' | (b) (4), (b) (6) | 28 Aug 2020 12:53:37 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2017' | (b) (4), (b) (6) | 28 Aug 2020 12:53:37 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:53:37 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 12:53:37 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:53:07

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2017' | (b) (4), (b) (6) | 28 Aug 2020 12:53:37 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:53:37 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2017' | System | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2017' | System | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:53:07

Condition

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:56:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 12:56:43 |
| Data point term sent to Coder | System | 28 Aug 2020 12:55:50 |
| User entered 'obesity' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 12:55:03 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '1' | (b) (4), (b) (6) | 28 Aug 2020 12:55:03 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 12:55:03 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:53:07

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2008' | (b) (4), (b) (6) | 28 Aug 2020 12:55:03 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:55:03 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2008' | System | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2008' | System | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM). | (b) (4), (b) (6) | 15 Oct 2020 21:52:53 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0. | Coder Import (b) (4) | 24 Sep 2020 01:06:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | (b) (4) | 24 Sep 2020 01:06:42 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'no meds per patient' (Site from DM). | Dawn Killian (b) (4) | 24 Sep 2020 01:05:29 |
| Data point term sent to Coder | System | 24 Sep 2020 01:05:27 |
| Coding entries removed. | Dawn Killian (b) (4) | 24 Sep 2020 01:05:16 |
| User entered 'Type II Diabetes' reason for change: Data Entry Error | Dawn Killian (b) (4) | 24 Sep 2020 01:05:16 |
| 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) | 09 Sep 2020 19:21:48 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0. | Coder Import (b) (4) | 28 Aug 2020 15:19:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | (b) (4) | 28 Aug 2020 15:19:46 |
| Data point term sent to Coder | System | 28 Aug 2020 12:56:50 |

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered 'DMII' | (b) (4), (b) (6) | 28 Aug 2020 12:55:53 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 1999' | (b) (4), (b) (6) | 28 Aug 2020 12:55:53 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:55:53 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 12:55:53 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 12:55:53 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:55:53 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1999' | System | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1999' | System | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:53:07

Condition

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Intraductal proliferative breast lesion, LLT: Ductal carcinoma in situ - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Aug 2020 21:03:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Aug 2020 21:03:37 |
| Data point term sent to Coder | System | 28 Aug 2020 12:56:53 |
| User entered 'bilateral breast ductal carcinoma in situ' | (b) (4), (b) (6) | 28 Aug 2020 12:56:33 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2014' | (b) (4), (b) (6) | 28 Aug 2020 12:56:33 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:56:33 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 12:56:33 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2014' | (b) (4), (b) (6) | 28 Aug 2020 12:56:33 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:56:33 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2014' | System | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2014' | System | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Papillary thyroid cancer, LLT: Papillary thyroid cancer - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 29 Aug 2020 06:21:32 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 29 Aug 2020 06:21:32 |
| Data point term sent to Coder | System | 28 Aug 2020 13:00:00 |
| User entered 'thyroid gland papillary cancer' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered 'UN UNK 2014' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Aug 2020 12:59:42 |
| User entered 'un UNK 1973' | (b) (4), (b) (6) | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:59:28 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 12:59:28 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered 'UN UNK 2014' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Aug 2020 12:59:42 |
| User entered 'un UNK 1973' | (b) (4), (b) (6) | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 12:59:28 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 28 Aug 2020 12:59:42 |
| User entered 'Jan 1973' | System | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2014' | System | 28 Aug 2020 12:59:42 |
| User entered '1973' | System | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 28 Aug 2020 12:59:42 |
| User entered 'Jan 1973' | System | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2014' | System | 28 Aug 2020 12:59:42 |
| User entered '1973' | System | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 13:01:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 13:01:48 |
| Data point term sent to Coder | System | 28 Aug 2020 13:01:03 |
| User entered 'uterine fibroids' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2005' | (b) (4), (b) (6) | 28 Aug 2020 13:00:27 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:00:27 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:00:27 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2005' | (b) (4), (b) (6) | 28 Aug 2020 13:00:27 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:00:27 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2005' | System | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2005' | System | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 13:01:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 13:01:48 |
| Data point term sent to Coder | System | 28 Aug 2020 13:01:02 |
| User entered 'osteoarthritis bilateral knees' | (b) (4), (b) (6) | 28 Aug 2020 13:00:05 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 1973' | (b) (4), (b) (6) | 28 Aug 2020 13:00:05 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:00:05 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:00:05 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:53:07

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:00:05 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:00:05 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1973' | System | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1973' | System | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:53:07

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femur fracture, LLT: Femur fracture - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Sep 2020 01:06:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Sep 2020 01:06:42 |
| Data point term sent to Coder | System | 24 Sep 2020 01:05:27 |
| User entered 'left femur fracture' | Dawn Killian (b) (4) | 24 Sep 2020 01:04:41 |
| | (b) (4) | |

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'UN UNK 2015' | Dawn Killian (b) (4) (b) (4) | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:53:07

Start date completely unknown

| Audit | User | Time (GMT) |
|------------------|---------------------------------|----------------------|
| User entered '0' | Dawn Killian (b) (4) (b) (4) | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:53:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Dawn Killian (b) (4) (b) (4) | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'UN UNK 2015' | Dawn Killian (b) (4) (b) (4) | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:53:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|---------------------------------|----------------------|
| User entered '0' | Dawn Killian (b) (4) (b) (4) | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2015' | System | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2015' | System | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2015' | System | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2015' | System | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System | 28 Aug 2020 13:01:45 |
| Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System). | System | 28 Aug 2020 13:01:45 |
| User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System). | System | 28 Aug 2020 13:01:45 |
| User entered '27 Aug 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Aug 2020 13:01:45 |
| User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System | 28 Aug 2020 13:01:08 |
| User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System). | System | 28 Aug 2020 13:01:08 |
| User entered '25 Aug 2020' | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '08:44' | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 08:44' | System | 28 Aug 2020 13:01:45 |
| User entered '25 Aug 2020 08:44' | System | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| User entered '163.0' cm | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |
| | | |
| DataPoint set to visible. | System | 27 Aug 2020 15:42:56 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| User entered '93.5' kg | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |
| | | |
| DataPoint set to visible. | System | 27 Aug 2020 15:42:56 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------|----------------------|
| User entered '35.19139' | System | 28 Aug 2020 13:01:08 |
| DataPoint set to visible. | System | 27 Aug 2020 15:42:56 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|--------|----------------------|
| User entered 'kg/m2' | System | 28 Aug 2020 13:01:08 |
| DataPoint set to visible. | System | 27 Aug 2020 15:42:56 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| User entered 'Other (Other)' | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:01:08 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:07

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:01:58 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:07

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 28 Aug 2020 13:01:58 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 28 Aug 2020 13:02:26 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:07

Is the participant of childbearing potential?

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:26 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Surgically sterile (SURGICALLY STERILE)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:26 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:07

If Partner medically sterile or Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:02:26 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:07

If Surgically sterile, date of surgery (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2005' | (b) (4), (b) (6) | 28 Aug 2020 13:02:26 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:07

Date of surgery unknown

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:02:26 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:02:26 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:07

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:02:26 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

[Other](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

No Risk Identified

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '1' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

[Other](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:07

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:02:46 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:03:24 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 28 Aug 2020 13:03:24 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 28 Aug 2020 13:03:24 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 28 Aug 2020 13:03:24 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:07

What was the date of randomization? (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| User entered '27 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) <div></div> | 27 Aug 2020 15:09:35 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:07

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|-----------------------|---|----------------------|
| User entered '188281' | RWS_ENDPOINT ENDPOINT (b) (4) <div></div> | 27 Aug 2020 15:09:35 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:07

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|-------------------------------|--|----------------------|
| User entered '>=65 years (3)' | RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 27 Aug 2020 15:09:35 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:07

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:03:50 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:07

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:03:50 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:07

Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:03:50 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:07

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Dawn Killian (b) (4) | 31 Aug 2020 19:02:07 |
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:03:50 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:07

[Liver Disease](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:03:50 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:07

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 08:12:41 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 08:12:40 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:07

Height

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:07

Weight

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:07

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:07

Weight

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '09:25' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 09:25' | System | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered '036.8' C | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '065' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '016' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '131' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '081' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:07

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:07

Weight

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '11:00' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:00' | System | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered '036.7' C | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '066' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '012' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '120' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '076' | (b) (4), (b) (6) | 28 Aug 2020 13:08:19 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:07

Was the physical examination performed?

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:08:41 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:07

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:08:41 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '27 Aug 2020' | Nathan Cortez (b) (4) [REDACTED] | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|-------------------------------------|----------------------|
| User entered '10:30' | Nathan Cortez (b) (4) [REDACTED] | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 10:30' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Nathan Cortez (b) (4) | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:10:39 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 28 Aug 2020 13:10:39 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '09:36' | (b) (4), (b) (6) | 28 Aug 2020 13:10:39 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 09:36' | System | 28 Aug 2020 13:10:39 |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:53:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 28 Aug 2020 13:10:54 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:07

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 28 Aug 2020 13:10:54 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:10:54 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:07

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '09:47' | (b) (4), (b) (6) | 28 Aug 2020 13:10:54 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:07

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 09:47' | System | 28 Aug 2020 13:10:54 |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:07

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 28 Aug 2020 13:10:54 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:10:54 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:07

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:10:54 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:07

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Aug 2020 13:10:54 |

US3292324

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:10:59 |
| | | |
| | | |

US3292324

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 28 Aug 2020 13:10:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:03:23', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '979191b1-1b26-41d1-af4b-5fec81e5f0c2' | System | 27 Aug 2020 16:04:15 |
| User entered 'Yes (Y)' | System | 27 Aug 2020 16:04:15 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:03:31', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '979191b1-1b26-41d1-af4b-5fec81e5f0c2' | System | 27 Aug 2020 16:04:15 |
| User entered '98.0' | System | 27 Aug 2020 16:04:15 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:03:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '979191b1-1b26-41d1-af4b-5fec81e5f0c2' | System | 27 Aug 2020 16:04:15 |
| User entered 'No (N)' | System | 27 Aug 2020 16:04:15 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:03:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '979191b1-1b26-41d1-af4b-5fec81e5f0c2' | System | 27 Aug 2020 16:04:15 |
| User entered '27 Aug 2020 11:03' | System | 27 Aug 2020 16:04:15 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 10:50' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 13:20' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, after vaccination (at home)' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:17', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0f4874c4-7620-4a4e-8110-e0bfb1c1aeaa' | System | 28 Aug 2020 00:29:46 |
| User entered 'Yes (Y)' | System | 28 Aug 2020 00:29:46 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0f4874c4-7620-4a4e-8110-e0bfb1c1aeaa' | System | 28 Aug 2020 00:29:46 |
| User entered '98.8' | System | 28 Aug 2020 00:29:46 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0f4874c4-7620-4a4e-8110-e0bfb1c1aeaa' | System | 28 Aug 2020 00:29:46 |
| User entered 'No (N)' | System | 28 Aug 2020 00:29:46 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0f4874c4-7620-4a4e-8110-e0bfb1c1aeaa' | System | 28 Aug 2020 00:29:46 |
| User entered '27 Aug 2020 19:29' | System | 28 Aug 2020 00:29:46 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 14:15' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 2' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:52:37', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'a1456587-b9ee-4cc1-a1cf-eb83054ba076' | System | 28 Aug 2020 23:52:58 |
| User entered 'Yes (Y)' | System | 28 Aug 2020 23:52:58 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:52:44', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'a1456587-b9ee-4cc1-a1cf-eb83054ba076' | System | 28 Aug 2020 23:52:58 |
| User entered '98.8' | System | 28 Aug 2020 23:52:58 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:52:50', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'a1456587-b9ee-4cc1-a1cf-eb83054ba076' | System | 28 Aug 2020 23:52:58 |
| User entered 'No (N)' | System | 28 Aug 2020 23:52:58 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:52:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'a1456587-b9ee-4cc1-a1cf-eb83054ba076' | System | 28 Aug 2020 23:52:58 |
| User entered '28 Aug 2020 18:52' | System | 28 Aug 2020 23:52:58 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 3' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:40:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e788488e-ba41-4a61-b5b8-8be666886c01' | System | 30 Aug 2020 12:41:28 |
| User entered 'Yes (Y)' | System | 30 Aug 2020 12:41:28 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e788488e-ba41-4a61-b5b8-8be666886c01' | System | 30 Aug 2020 12:41:28 |
| User entered '97.7' | System | 30 Aug 2020 12:41:28 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e788488e-ba41-4a61-b5b8-8be666886c01' | System | 30 Aug 2020 12:41:28 |
| User entered 'No (N)' | System | 30 Aug 2020 12:41:28 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e788488e-ba41-4a61-b5b8-8be666886c01' | System | 30 Aug 2020 12:41:28 |
| User entered '30 Aug 2020 07:41' | System | 30 Aug 2020 12:41:28 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 4' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:58:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8acb70dd-ca55-4707-9042-9d1e3cd4c58a' | System | 31 Aug 2020 00:58:59 |
| User entered 'Yes (Y)' | System | 31 Aug 2020 00:58:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:58:46', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8acb70dd-ca55-4707-9042-9d1e3cd4c58a' | System | 31 Aug 2020 00:58:59 |
| User entered '99.0' | System | 31 Aug 2020 00:58:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:58:49', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8acb70dd-ca55-4707-9042-9d1e3cd4c58a' | System | 31 Aug 2020 00:58:59 |
| User entered 'No (N)' | System | 31 Aug 2020 00:58:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:58:56', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8acb70dd-ca55-4707-9042-9d1e3cd4c58a' User entered '30 Aug 2020 19:58' | System | 31 Aug 2020 00:58:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 5' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0e30235c-22ca-43c1-ad7a-a2abdb9b162d' | System | 01 Sep 2020 01:07:29 |
| User entered 'Yes (Y)' | System | 01 Sep 2020 01:07:29 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0e30235c-22ca-43c1-ad7a-a2abdb9b162d' | System | 01 Sep 2020 01:07:29 |
| User entered '97.8' | System | 01 Sep 2020 01:07:29 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:23', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0e30235c-22ca-43c1-ad7a-a2abdb9b162d' | System | 01 Sep 2020 01:07:29 |
| User entered 'No (N)' | System | 01 Sep 2020 01:07:29 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0e30235c-22ca-43c1-ad7a-a2abdb9b162d' User entered '31 Aug 2020 20:07' | System | 01 Sep 2020 01:07:29 |
| | System | 01 Sep 2020 01:07:29 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 6' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:54:13', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4f9b8de-8a4c-4001-bb3f-ed178adf6191' | System | 02 Sep 2020 01:54:41 |
| User entered 'Yes (Y)' | System | 02 Sep 2020 01:54:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:54:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4f9b8de-8a4c-4001-bb3f-ed178adf6191' | System | 02 Sep 2020 01:54:41 |
| User entered '98.1' | System | 02 Sep 2020 01:54:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:54:29', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4f9b8de-8a4c-4001-bb3f-ed178adf6191' | System | 02 Sep 2020 01:54:41 |
| User entered 'No (N)' | System | 02 Sep 2020 01:54:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:54:39', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4f9b8de-8a4c-4001-bb3f-ed178adf6191' | System | 02 Sep 2020 01:54:41 |
| User entered '01 Sep 2020 20:54' | System | 02 Sep 2020 01:54:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 7' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:45:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '469c7d17-9f94-448d-930d-d58eeeb612d3' | System | 03 Sep 2020 00:46:38 |
| User entered 'Yes (Y)' | System | 03 Sep 2020 00:46:38 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:22', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '469c7d17-9f94-448d-930d-d58eeeb612d3' | System | 03 Sep 2020 00:46:38 |
| User entered '98.2' | System | 03 Sep 2020 00:46:38 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '469c7d17-9f94-448d-930d-d58eeeb612d3' | System | 03 Sep 2020 00:46:38 |
| User entered 'No (N)' | System | 03 Sep 2020 00:46:38 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '469c7d17-9f94-448d-930d-d58eeeb612d3' | System | 03 Sep 2020 00:46:38 |
| User entered '02 Sep 2020 19:46' | System | 03 Sep 2020 00:46:38 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:04', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c4341e38-81c0-4949-8969-0d0958724f84' | System | 27 Aug 2020 16:04:23 |
| User entered 'None (1)' | System | 27 Aug 2020 16:04:23 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c4341e38-81c0-4949-8969-0d0958724f84' | System | 27 Aug 2020 16:04:23 |
| User entered 'No (N)' | System | 27 Aug 2020 16:04:23 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:10', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c4341e38-81c0-4949-8969-0d0958724f84' | System | 27 Aug 2020 16:04:23 |
| User entered 'No (N)' | System | 27 Aug 2020 16:04:23 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c4341e38-81c0-4949-8969-0d0958724f84' | System | 27 Aug 2020 16:04:23 |
| User entered 'None (1)' | System | 27 Aug 2020 16:04:23 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c4341e38-81c0-4949-8969-0d0958724f84' | System | 27 Aug 2020 16:04:23 |
| User entered '27 Aug 2020 11:04' | System | 27 Aug 2020 16:04:23 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 10:50' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 13:20' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, after vaccination (at home)' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4e4cd01-933b-495a-a233-40fadab277c8' | System | 28 Aug 2020 00:30:07 |
| User entered 'None (1)' | System | 28 Aug 2020 00:30:07 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:51', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4e4cd01-933b-495a-a233-40fadab277c8' | System | 28 Aug 2020 00:30:07 |
| User entered 'No (N)' | System | 28 Aug 2020 00:30:07 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4e4cd01-933b-495a-a233-40fadab277c8' | System | 28 Aug 2020 00:30:07 |
| User entered 'No (N)' | System | 28 Aug 2020 00:30:07 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:59', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4e4cd01-933b-495a-a233-40fadab277c8' | System | 28 Aug 2020 00:30:07 |
| User entered 'None (1)' | System | 28 Aug 2020 00:30:07 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:03', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4e4cd01-933b-495a-a233-40fadab277c8' | System | 28 Aug 2020 00:30:07 |
| User entered '27 Aug 2020 19:30' | System | 28 Aug 2020 00:30:07 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 14:15' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 2' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:12', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '1a0d9601-9259-4884-9dd7-dc70ea6f8c20' | System | 28 Aug 2020 23:53:41 |
| User entered 'Does not interfere with activity (2)' | System | 28 Aug 2020 23:53:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:17', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '1a0d9601-9259-4884-9dd7-dc70ea6f8c20' | System | 28 Aug 2020 23:53:41 |
| User entered 'No (N)' | System | 28 Aug 2020 23:53:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '1a0d9601-9259-4884-9dd7-dc70ea6f8c20' | System | 28 Aug 2020 23:53:41 |
| User entered 'No (N)' | System | 28 Aug 2020 23:53:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:29', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '1a0d9601-9259-4884-9dd7-dc70ea6f8c20' | System | 28 Aug 2020 23:53:41 |
| User entered 'None (1)' | System | 28 Aug 2020 23:53:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:37', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '1a0d9601-9259-4884-9dd7-dc70ea6f8c20' | System | 28 Aug 2020 23:53:41 |
| User entered '28 Aug 2020 18:53' | System | 28 Aug 2020 23:53:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 3' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2fcf7b67-cfda-48ab-99e8-9865e8a6c5c9' | System | 30 Aug 2020 12:41:49 |
| User entered 'None (1)' | System | 30 Aug 2020 12:41:49 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:34', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2fcf7b67-cfda-48ab-99e8-9865e8a6c5c9' | System | 30 Aug 2020 12:41:49 |
| User entered 'No (N)' | System | 30 Aug 2020 12:41:49 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:37', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2fcf7b67-cfda-48ab-99e8-9865e8a6c5c9' | System | 30 Aug 2020 12:41:49 |
| User entered 'No (N)' | System | 30 Aug 2020 12:41:49 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2fcf7b67-cfda-48ab-99e8-9865e8a6c5c9' | System | 30 Aug 2020 12:41:49 |
| User entered 'None (1)' | System | 30 Aug 2020 12:41:49 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2fcf7b67-cfda-48ab-99e8-9865e8a6c5c9' User entered '30 Aug 2020 07:41' | System | 30 Aug 2020 12:41:49 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 4' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:06', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '72ee69fe-3ff0-4d32-bd6f-2dd77128a1c7' | System | 31 Aug 2020 00:59:27 |
| User entered 'None (1)' | System | 31 Aug 2020 00:59:27 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:09', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '72ee69fe-3ff0-4d32-bd6f-2dd77128a1c7' | System | 31 Aug 2020 00:59:27 |
| User entered 'No (N)' | System | 31 Aug 2020 00:59:27 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:12', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '72ee69fe-3ff0-4d32-bd6f-2dd77128a1c7' | System | 31 Aug 2020 00:59:27 |
| User entered 'No (N)' | System | 31 Aug 2020 00:59:27 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '72ee69fe-3ff0-4d32-bd6f-2dd77128a1c7' | System | 31 Aug 2020 00:59:27 |
| User entered 'None (1)' | System | 31 Aug 2020 00:59:27 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:22', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '72ee69fe-3ff0-4d32-bd6f-2dd77128a1c7' | System | 31 Aug 2020 00:59:27 |
| User entered '30 Aug 2020 19:59' | System | 31 Aug 2020 00:59:27 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 5' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4201afb6-09c6-4212-839b-48eb1754be6d' User entered 'None (1)' | System | 01 Sep 2020 01:07:57 |
| | System | 01 Sep 2020 01:07:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4201afb6-09c6-4212-839b-48eb1754be6d' | System | 01 Sep 2020 01:07:57 |
| User entered 'No (N)' | System | 01 Sep 2020 01:07:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4201afb6-09c6-4212-839b-48eb1754be6d' | System | 01 Sep 2020 01:07:57 |
| User entered 'No (N)' | System | 01 Sep 2020 01:07:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4201afb6-09c6-4212-839b-48eb1754be6d' User entered 'None (1)' | System | 01 Sep 2020 01:07:57 |
| | System | 01 Sep 2020 01:07:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4201afb6-09c6-4212-839b-48eb1754be6d' | System | 01 Sep 2020 01:07:57 |
| User entered '31 Aug 2020 20:07' | System | 01 Sep 2020 01:07:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 6' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:54:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ac295084-defb-4598-a1ef-6cc27fac160e' | System | 02 Sep 2020 01:55:51 |
| User entered 'None (1)' | System | 02 Sep 2020 01:55:51 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:55:11', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ac295084-defb-4598-a1ef-6cc27fac160e' | System | 02 Sep 2020 01:55:51 |
| User entered 'No (N)' | System | 02 Sep 2020 01:55:51 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:55:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ac295084-defb-4598-a1ef-6cc27fac160e' | System | 02 Sep 2020 01:55:51 |
| User entered 'No (N)' | System | 02 Sep 2020 01:55:51 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:55:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ac295084-defb-4598-a1ef-6cc27fac160e' User entered 'None (1)' | System | 02 Sep 2020 01:55:51 |
| | System | 02 Sep 2020 01:55:51 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:55:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ac295084-defb-4598-a1ef-6cc27fac160e' | System | 02 Sep 2020 01:55:51 |
| User entered '01 Sep 2020 20:55' | System | 02 Sep 2020 01:55:51 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 7' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '36c211c5-ed35-415f-bc34-c7fee1ddf55c' | System | 03 Sep 2020 00:46:57 |
| User entered 'None (1)' | System | 03 Sep 2020 00:46:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '36c211c5-ed35-415f-bc34-c7fee1ddf55c' | System | 03 Sep 2020 00:46:57 |
| User entered 'No (N)' | System | 03 Sep 2020 00:46:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '36c211c5-ed35-415f-bc34-c7fee1ddf55c' | System | 03 Sep 2020 00:46:57 |
| User entered 'No (N)' | System | 03 Sep 2020 00:46:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '36c211c5-ed35-415f-bc34-c7fee1ddf55c' | System | 03 Sep 2020 00:46:57 |
| User entered 'None (1)' | System | 03 Sep 2020 00:46:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '36c211c5-ed35-415f-bc34-c7fee1ddf55c' | System | 03 Sep 2020 00:46:57 |
| User entered '02 Sep 2020 19:46' | System | 03 Sep 2020 00:46:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' | System | 27 Aug 2020 16:04:59 |
| User entered 'None (0)' | System | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' | System | 27 Aug 2020 16:04:59 |
| User entered 'None (0)' | System | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' | System | 27 Aug 2020 16:04:59 |
| User entered 'None (0)' | System | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' | System | 27 Aug 2020 16:04:59 |
| User entered 'None (0)' | System | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' | System | 27 Aug 2020 16:04:59 |
| User entered 'None (0)' | System | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' | System | 27 Aug 2020 16:04:59 |
| User entered 'None (0)' | System | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' | System | 27 Aug 2020 16:04:59 |
| User entered 'No (N)' | System | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' User entered '27 Aug 2020 11:04' | System | 27 Aug 2020 16:04:59 |
| | System | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 10:50' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 13:20' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, after vaccination (at home)' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' | System | 28 Aug 2020 00:30:50 |
| User entered 'None (0)' | System | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:21', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' | System | 28 Aug 2020 00:30:50 |
| User entered 'None (0)' | System | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' | System | 28 Aug 2020 00:30:50 |
| User entered 'None (0)' | System | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:29', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' | System | 28 Aug 2020 00:30:50 |
| User entered 'None (0)' | System | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' | System | 28 Aug 2020 00:30:50 |
| User entered 'None (0)' | System | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' | System | 28 Aug 2020 00:30:50 |
| User entered 'None (0)' | System | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' | System | 28 Aug 2020 00:30:50 |
| User entered 'No (N)' | System | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' | System | 28 Aug 2020 00:30:50 |
| User entered '27 Aug 2020 19:30' | System | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 14:15' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 2' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:43', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' | System | 28 Aug 2020 23:54:45 |
| User entered 'None (0)' | System | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' | System | 28 Aug 2020 23:54:45 |
| User entered 'None (0)' | System | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:59', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' | System | 28 Aug 2020 23:54:45 |
| User entered 'None (0)' | System | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:03', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' | System | 28 Aug 2020 23:54:45 |
| User entered 'None (0)' | System | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:06', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' | System | 28 Aug 2020 23:54:45 |
| User entered 'None (0)' | System | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:09', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' | System | 28 Aug 2020 23:54:45 |
| User entered 'None (0)' | System | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' | System | 28 Aug 2020 23:54:45 |
| User entered 'No (N)' | System | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' User entered '28 Aug 2020 18:54' | System | 28 Aug 2020 23:54:45 |
| | System | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 3' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:50', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' | System | 30 Aug 2020 12:44:20 |
| User entered 'None (0)' | System | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' | System | 30 Aug 2020 12:44:20 |
| User entered 'None (0)' | System | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:58', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' | System | 30 Aug 2020 12:44:20 |
| User entered 'None (0)' | System | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:42:03', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' | System | 30 Aug 2020 12:44:20 |
| User entered 'None (0)' | System | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:42:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' | System | 30 Aug 2020 12:44:20 |
| User entered 'None (0)' | System | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:42:11', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' | System | 30 Aug 2020 12:44:20 |
| User entered 'None (0)' | System | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:42:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' | System | 30 Aug 2020 12:44:20 |
| User entered 'No (N)' | System | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:42:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' | System | 30 Aug 2020 12:44:20 |
| User entered '30 Aug 2020 07:42' | System | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 4' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System | 31 Aug 2020 00:59:59 |
| User entered 'None (0)' | System | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System | 31 Aug 2020 00:59:59 |
| User entered 'None (0)' | System | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System | 31 Aug 2020 00:59:59 |
| User entered 'None (0)' | System | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System | 31 Aug 2020 00:59:59 |
| User entered 'None (0)' | System | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System | 31 Aug 2020 00:59:59 |
| User entered 'None (0)' | System | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System | 31 Aug 2020 00:59:59 |
| User entered 'None (0)' | System | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:50', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System | 31 Aug 2020 00:59:59 |
| User entered 'No (N)' | System | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System | 31 Aug 2020 00:59:59 |
| User entered '30 Aug 2020 19:59' | System | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 5' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' | System | 01 Sep 2020 01:10:17 |
| User entered 'None (0)' | System | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:03', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' | System | 01 Sep 2020 01:10:17 |
| User entered 'None (0)' | System | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' | System | 01 Sep 2020 01:10:17 |
| User entered 'None (0)' | System | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:09', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' | System | 01 Sep 2020 01:10:17 |
| User entered 'None (0)' | System | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:21', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' | System | 01 Sep 2020 01:10:17 |
| User entered 'None (0)' | System | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:34', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' | System | 01 Sep 2020 01:10:17 |
| User entered 'None (0)' | System | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:10:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' | System | 01 Sep 2020 01:10:17 |
| User entered 'No (N)' | System | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:10:15', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' | System | 01 Sep 2020 01:10:17 |
| User entered '31 Aug 2020 20:10' | System | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 6' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:56:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' | System | 02 Sep 2020 01:57:17 |
| User entered 'None (0)' | System | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:56:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' | System | 02 Sep 2020 01:57:17 |
| User entered 'None (0)' | System | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:56:20', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' | System | 02 Sep 2020 01:57:17 |
| User entered 'None (0)' | System | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:56:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' | System | 02 Sep 2020 01:57:17 |
| User entered 'None (0)' | System | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:56:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' | System | 02 Sep 2020 01:57:17 |
| User entered 'None (0)' | System | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:57:04', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' | System | 02 Sep 2020 01:57:17 |
| User entered 'None (0)' | System | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:57:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' | System | 02 Sep 2020 01:57:17 |
| User entered 'No (N)' | System | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:57:15', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' | System | 02 Sep 2020 01:57:17 |
| User entered '01 Sep 2020 20:57' | System | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 7' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' | System | 03 Sep 2020 00:47:18 |
| User entered 'None (0)' | System | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' | System | 03 Sep 2020 00:47:18 |
| User entered 'None (0)' | System | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:02', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' | System | 03 Sep 2020 00:47:18 |
| User entered 'None (0)' | System | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:05', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' | System | 03 Sep 2020 00:47:18 |
| User entered 'None (0)' | System | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' | System | 03 Sep 2020 00:47:18 |
| User entered 'None (0)' | System | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:10', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' | System | 03 Sep 2020 00:47:18 |
| User entered 'None (0)' | System | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:13', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' | System | 03 Sep 2020 00:47:18 |
| User entered 'No (N)' | System | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' | System | 03 Sep 2020 00:47:18 |
| User entered '02 Sep 2020 19:47' | System | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 12:00' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 03 Sep 2020 16:52:15 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User entered '03 Sep 2020' reason for change: New Information | Antonio Gutierrez (b) (4) | 10 Nov 2020 15:47:03 |
| User entered '3 Sep 2020' | Kristy Trevino (b) (4) | 03 Sep 2020 16:52:15 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 03 Sep 2020 16:52:15 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 03 Sep 2020 16:52:15 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 03 Sep 2020 16:52:23 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 03 Sep 2020 16:52:23 |

US3292324

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------|----------------------|
| User entered 'Yes (Y)' | Antonio Gutierrez (b) (4) | 06 Nov 2020 15:47:25 |

US3292324

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| User entered '10 Sep 2020' | Antonio Gutierrez (b) (4) | 06 Nov 2020 15:47:25 |

US3292324

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User entered 'Contact Not Made (CONTACT NOT MADE)' | Antonio Gutierrez (b) (4) | 06 Nov 2020 15:47:25 |

US3292324

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User entered 'Attempts were made, but staff unable to contact patient' | Antonio Gutierrez (b) (4) | 06 Nov 2020 15:47:25 |

US3292324

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) [REDACTED] | 24 Sep 2020 15:04:34 |

US3292324

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Sep 2020 15:04:34 |

US3292324

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 02 Oct 2020 16:54:14 |

US3292324

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '18 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 02 Oct 2020 16:54:14 |

US3292324

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Gerardo Pena (b) (4) (b) (4) | 02 Oct 2020 16:54:14 |

US3292324

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 02 Oct 2020 16:54:14 |

US3292324

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) [REDACTED] | 24 Sep 2020 15:04:42 |

US3292324

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Sep 2020 15:04:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:06:41 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '24 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:06:41 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:06:41 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 24 Sep 2020 16:06:41 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

Were vital signs assessed?

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '24 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| User entered '09:15' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 09:15' | System | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered '36.9' C | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (Oral)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '67' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '12' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|---------------------------------|----------------------|
| User entered '115' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '64' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:07

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

Were vital signs assessed?

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '24 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| User entered '10:29' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 10:29' | System | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered '36.6' C | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (Oral)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '68' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '12' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|---------------------------------|----------------------|
| User entered '117' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '74' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:07

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:07

Was the physical examination performed?

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:22 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:07

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '24 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:22 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | Nathan Cortez (b) (4) [REDACTED] | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Nathan Cortez (b) (4) [REDACTED] | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User entered '24 Sep 2020' | Nathan Cortez (b) (4) | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|-------------------------------------|----------------------|
| User entered '09:59' | Nathan Cortez (b) (4) [REDACTED] | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 09:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Nathan Cortez (b) (4) | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:07

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:37 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '24 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:37 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| User entered '09:22' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:37 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 09:22' | System | 24 Sep 2020 16:11:37 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:53:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '24 Sep 2020' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:07

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:07

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| User entered '09:40' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:07

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 09:40' | System | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:07

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:07

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:07

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 24 Sep 2020 16:12:02 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Sep 2020 16:12:02 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:31:39', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e412fe7c-0b74-4b2e-9247-7f8259a46ef0' | System | 24 Sep 2020 15:32:02 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 15:32:02 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:31:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e412fe7c-0b74-4b2e-9247-7f8259a46ef0' | System | 24 Sep 2020 15:32:02 |
| User entered '97.8' | System | 24 Sep 2020 15:32:02 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:31:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e412fe7c-0b74-4b2e-9247-7f8259a46ef0' | System | 24 Sep 2020 15:32:02 |
| User entered 'No (N)' | System | 24 Sep 2020 15:32:02 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e412fe7c-0b74-4b2e-9247-7f8259a46ef0' User entered '24 Sep 2020 10:32' | System | 24 Sep 2020 15:32:02 |
| | System | 24 Sep 2020 15:32:02 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 10:19' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:49' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:48:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '31a605f0-70bb-4e14-a7e7-7cd768c0d85b' | System | 25 Sep 2020 00:49:14 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 00:49:14 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:05', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '31a605f0-70bb-4e14-a7e7-7cd768c0d85b' User entered '97.9' | System | 25 Sep 2020 00:49:14 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '31a605f0-70bb-4e14-a7e7-7cd768c0d85b' | System | 25 Sep 2020 00:49:14 |
| User entered 'No (N)' | System | 25 Sep 2020 00:49:14 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:11', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '31a605f0-70bb-4e14-a7e7-7cd768c0d85b' User entered '24 Sep 2020 19:49' | System | 25 Sep 2020 00:49:14 |
| | System | 25 Sep 2020 00:49:14 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 13:44' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 2' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:30:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f' | System | 25 Sep 2020 23:32:37 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 23:32:37 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:12', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f' | System | 25 Sep 2020 23:32:37 |
| User entered '99.6' | System | 25 Sep 2020 23:32:37 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f' | System | 25 Sep 2020 23:32:37 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 23:32:37 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). 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 'will ask at next phone call' (Site from System). | (b) (4), (b) (6) | 11 Nov 2020 12:20:43 |
| 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.' answered with 'will ask at next phone call' (Site from System). | Dawn Killian (b) (4) | 28 Sep 2020 14:59:46 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 25 Sep 2020 23:32:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:27', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f' | System | 25 Sep 2020 23:32:37 |
| User entered '1' | System | 25 Sep 2020 23:32:37 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:27', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f' User entered '0' | System | 25 Sep 2020 23:32:37 |
| | System | 25 Sep 2020 23:32:37 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f' | System | 25 Sep 2020 23:32:37 |
| User entered '25 Sep 2020 18:32' | System | 25 Sep 2020 23:32:37 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 3' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7cf767d6-5415-4f58-83ee-fee5296b3607' | System | 27 Sep 2020 16:06:47 |
| User entered 'Yes (Y)' | System | 27 Sep 2020 16:06:47 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:37', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7cf767d6-5415-4f58-83ee-fee5296b3607' | System | 27 Sep 2020 16:06:47 |
| User entered '98.6' | System | 27 Sep 2020 16:06:47 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7cf767d6-5415-4f58-83ee-fee5296b3607' | System | 27 Sep 2020 16:06:47 |
| User entered 'No (N)' | System | 27 Sep 2020 16:06:47 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:44', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7cf767d6-5415-4f58-83ee-fee5296b3607' | System | 27 Sep 2020 16:06:47 |
| User entered '27 Sep 2020 11:06' | System | 27 Sep 2020 16:06:47 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 4' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:10', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8f405322-374a-4dd1-9059-fdbe38e9537f' | System | 28 Sep 2020 01:12:33 |
| User entered 'Yes (Y)' | System | 28 Sep 2020 01:12:33 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:21', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8f405322-374a-4dd1-9059-fdbe38e9537f' | System | 28 Sep 2020 01:12:33 |
| User entered '98.6' | System | 28 Sep 2020 01:12:33 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8f405322-374a-4dd1-9059-fdbe38e9537f' | System | 28 Sep 2020 01:12:33 |
| User entered 'No (N)' | System | 28 Sep 2020 01:12:33 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8f405322-374a-4dd1-9059-fdbe38e9537f' | System | 28 Sep 2020 01:12:33 |
| User entered '27 Sep 2020 20:12' | System | 28 Sep 2020 01:12:33 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 5' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T18:59:44', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '11d848b9-e425-4fb1-8e43-52a9b3b24d14' | System | 28 Sep 2020 23:59:59 |
| User entered 'Yes (Y)' | System | 28 Sep 2020 23:59:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T18:59:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '11d848b9-e425-4fb1-8e43-52a9b3b24d14' | System | 28 Sep 2020 23:59:59 |
| User entered '98.4' | System | 28 Sep 2020 23:59:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T18:59:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '11d848b9-e425-4fb1-8e43-52a9b3b24d14' | System | 28 Sep 2020 23:59:59 |
| User entered 'No (N)' | System | 28 Sep 2020 23:59:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T18:59:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '11d848b9-e425-4fb1-8e43-52a9b3b24d14' | System | 28 Sep 2020 23:59:59 |
| User entered '28 Sep 2020 18:59' | System | 28 Sep 2020 23:59:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 6' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:00:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '35cdf34c-4d59-468c-ae6-781133513dd4' | System | 30 Sep 2020 12:01:10 |
| User entered 'Yes (Y)' | System | 30 Sep 2020 12:01:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:02', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '35cdf34c-4d59-468c-ae6-781133513dd4' | System | 30 Sep 2020 12:01:10 |
| User entered '98.4' | System | 30 Sep 2020 12:01:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:06', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '35cdf34c-4d59-468c-ae6-781133513dd4' | System | 30 Sep 2020 12:01:10 |
| User entered 'No (N)' | System | 30 Sep 2020 12:01:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:09', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '35cdf34c-4d59-468c-ae6-781133513dd4' User entered '30 Sep 2020 07:01' | System | 30 Sep 2020 12:01:10 |
| | System | 30 Sep 2020 12:01:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 7' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:01:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'df3f73bc-b603-4e39-ac60-4ac28ab47dcc' | System | 01 Oct 2020 12:02:07 |
| User entered 'Yes (Y)' | System | 01 Oct 2020 12:02:07 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:01:58', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'df3f73bc-b603-4e39-ac60-4ac28ab47dcc' User entered '98.0' | System | 01 Oct 2020 12:02:07 |
| | System | 01 Oct 2020 12:02:07 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:01', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'df3f73bc-b603-4e39-ac60-4ac28ab47dcc' | System | 01 Oct 2020 12:02:07 |
| User entered 'No (N)' | System | 01 Oct 2020 12:02:07 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:04', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'df3f73bc-b603-4e39-ac60-4ac28ab47dcc' User entered '01 Oct 2020 07:02' | System | 01 Oct 2020 12:02:07 |
| | System | 01 Oct 2020 12:02:07 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:06', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '239fd9e5-97c5-405d-ade8-e441e6b435cb' User entered 'None (1)' | System | 24 Sep 2020 15:32:21 |
| | System | 24 Sep 2020 15:32:21 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:09', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '239fd9e5-97c5-405d-ade8-e441e6b435cb' | System | 24 Sep 2020 15:32:21 |
| User entered 'No (N)' | System | 24 Sep 2020 15:32:21 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:11', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '239fd9e5-97c5-405d-ade8-e441e6b435cb' | System | 24 Sep 2020 15:32:21 |
| User entered 'No (N)' | System | 24 Sep 2020 15:32:21 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:15', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '239fd9e5-97c5-405d-ade8-e441e6b435cb' User entered 'None (1)' | System | 24 Sep 2020 15:32:21 |
| | System | 24 Sep 2020 15:32:21 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '239fd9e5-97c5-405d-ade8-e441e6b435cb' User entered '24 Sep 2020 10:32' | System | 24 Sep 2020 15:32:21 |
| | System | 24 Sep 2020 15:32:21 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 10:19' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:49' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '30d70f4c-b342-4380-acfe-dade29cdb707' | System | 25 Sep 2020 00:49:27 |
| User entered 'None (1)' | System | 25 Sep 2020 00:49:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '30d70f4c-b342-4380-acfe-dade29cdb707' | System | 25 Sep 2020 00:49:27 |
| User entered 'No (N)' | System | 25 Sep 2020 00:49:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:20', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '30d70f4c-b342-4380-acfe-dade29cdb707' | System | 25 Sep 2020 00:49:27 |
| User entered 'No (N)' | System | 25 Sep 2020 00:49:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:23', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '30d70f4c-b342-4380-acfe-dade29cdb707' | System | 25 Sep 2020 00:49:27 |
| User entered 'None (1)' | System | 25 Sep 2020 00:49:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '30d70f4c-b342-4380-acfe-dade29cdb707' | System | 25 Sep 2020 00:49:27 |
| User entered '24 Sep 2020 19:49' | System | 25 Sep 2020 00:49:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 13:44' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 2' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5c387c2d-a09b-424b-9c1d-567dd96936d8' | System | 25 Sep 2020 23:33:01 |
| User entered 'None (1)' | System | 25 Sep 2020 23:33:01 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:44', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5c387c2d-a09b-424b-9c1d-567dd96936d8' | System | 25 Sep 2020 23:33:01 |
| User entered 'No (N)' | System | 25 Sep 2020 23:33:01 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:49', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5c387c2d-a09b-424b-9c1d-567dd96936d8' | System | 25 Sep 2020 23:33:01 |
| User entered 'No (N)' | System | 25 Sep 2020 23:33:01 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5c387c2d-a09b-424b-9c1d-567dd96936d8' | System | 25 Sep 2020 23:33:01 |
| User entered 'None (1)' | System | 25 Sep 2020 23:33:01 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:56', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5c387c2d-a09b-424b-9c1d-567dd96936d8' | System | 25 Sep 2020 23:33:01 |
| User entered '25 Sep 2020 18:32' | System | 25 Sep 2020 23:33:01 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 3' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:49', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5ca01f82-42d6-45d9-96e6-75b49968b956' | System | 27 Sep 2020 16:07:12 |
| User entered 'None (1)' | System | 27 Sep 2020 16:07:12 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:51', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5ca01f82-42d6-45d9-96e6-75b49968b956' | System | 27 Sep 2020 16:07:12 |
| User entered 'No (N)' | System | 27 Sep 2020 16:07:12 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5ca01f82-42d6-45d9-96e6-75b49968b956' | System | 27 Sep 2020 16:07:12 |
| User entered 'No (N)' | System | 27 Sep 2020 16:07:12 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:05', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5ca01f82-42d6-45d9-96e6-75b49968b956' | System | 27 Sep 2020 16:07:12 |
| User entered 'None (1)' | System | 27 Sep 2020 16:07:12 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5ca01f82-42d6-45d9-96e6-75b49968b956' User entered '27 Sep 2020 11:07' | System | 27 Sep 2020 16:07:12 |
| | System | 27 Sep 2020 16:07:12 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 4' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'afc91674-b162-4fc8-825f-86d28451a263' | System | 28 Sep 2020 01:12:48 |
| User entered 'None (1)' | System | 28 Sep 2020 01:12:48 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'afc91674-b162-4fc8-825f-86d28451a263' | System | 28 Sep 2020 01:12:48 |
| User entered 'No (N)' | System | 28 Sep 2020 01:12:48 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'afc91674-b162-4fc8-825f-86d28451a263' | System | 28 Sep 2020 01:12:48 |
| User entered 'No (N)' | System | 28 Sep 2020 01:12:48 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'afc91674-b162-4fc8-825f-86d28451a263' | System | 28 Sep 2020 01:12:48 |
| User entered 'None (1)' | System | 28 Sep 2020 01:12:48 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:44', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'afc91674-b162-4fc8-825f-86d28451a263' | System | 28 Sep 2020 01:12:48 |
| User entered '27 Sep 2020 20:12' | System | 28 Sep 2020 01:12:48 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 5' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T18:59:59', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2faa67b2-6bd5-441d-b626-3c64698c063c' | System | 29 Sep 2020 00:00:15 |
| User entered 'None (1)' | System | 29 Sep 2020 00:00:15 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:02', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2faa67b2-6bd5-441d-b626-3c64698c063c' | System | 29 Sep 2020 00:00:15 |
| User entered 'No (N)' | System | 29 Sep 2020 00:00:15 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:05', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2faa67b2-6bd5-441d-b626-3c64698c063c' | System | 29 Sep 2020 00:00:15 |
| User entered 'No (N)' | System | 29 Sep 2020 00:00:15 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:10', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2faa67b2-6bd5-441d-b626-3c64698c063c' | System | 29 Sep 2020 00:00:15 |
| User entered 'None (1)' | System | 29 Sep 2020 00:00:15 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:12', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2faa67b2-6bd5-441d-b626-3c64698c063c' | System | 29 Sep 2020 00:00:15 |
| User entered '28 Sep 2020 19:00' | System | 29 Sep 2020 00:00:15 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 6' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:12', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'af40d496-f541-4bbd-b64a-98164b324983' | System | 30 Sep 2020 12:01:27 |
| User entered 'None (1)' | System | 30 Sep 2020 12:01:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'af40d496-f541-4bbd-b64a-98164b324983' | System | 30 Sep 2020 12:01:27 |
| User entered 'No (N)' | System | 30 Sep 2020 12:01:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:20', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'af40d496-f541-4bbd-b64a-98164b324983' | System | 30 Sep 2020 12:01:27 |
| User entered 'No (N)' | System | 30 Sep 2020 12:01:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:23', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'af40d496-f541-4bbd-b64a-98164b324983' | System | 30 Sep 2020 12:01:27 |
| User entered 'None (1)' | System | 30 Sep 2020 12:01:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'af40d496-f541-4bbd-b64a-98164b324983' User entered '30 Sep 2020 07:01' | System | 30 Sep 2020 12:01:27 |
| | System | 30 Sep 2020 12:01:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 7' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '432e94ea-d37a-4dfd-be4e-bed1711bf712' | System | 01 Oct 2020 12:02:22 |
| User entered 'None (1)' | System | 01 Oct 2020 12:02:22 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:11', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '432e94ea-d37a-4dfd-be4e-bed1711bf712' | System | 01 Oct 2020 12:02:22 |
| User entered 'No (N)' | System | 01 Oct 2020 12:02:22 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:13', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '432e94ea-d37a-4dfd-be4e-bed1711bf712' | System | 01 Oct 2020 12:02:22 |
| User entered 'No (N)' | System | 01 Oct 2020 12:02:22 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:17', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '432e94ea-d37a-4dfd-be4e-bed1711bf712' | System | 01 Oct 2020 12:02:22 |
| User entered 'None (1)' | System | 01 Oct 2020 12:02:22 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '432e94ea-d37a-4dfd-be4e-bed1711bf712' | System | 01 Oct 2020 12:02:22 |
| User entered '01 Oct 2020 07:02' | System | 01 Oct 2020 12:02:22 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:22', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' | System | 24 Sep 2020 15:32:46 |
| User entered 'None (0)' | System | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:27', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'None (0)' | System | 24 Sep 2020 15:32:46 |
| | System | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:29', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'None (0)' | System | 24 Sep 2020 15:32:46 |
| | System | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:31', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'None (0)' | System | 24 Sep 2020 15:32:46 |
| | System | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'None (0)' | System | 24 Sep 2020 15:32:46 |
| | System | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'None (0)' | System | 24 Sep 2020 15:32:46 |
| | System | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' | System | 24 Sep 2020 15:32:46 |
| User entered 'No (N)' | System | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:43', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered '24 Sep 2020 10:32' | System | 24 Sep 2020 15:32:46 |
| | System | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 10:19' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:49' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:30', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' | System | 25 Sep 2020 00:49:56 |
| User entered 'None (0)' | System | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' | System | 25 Sep 2020 00:49:56 |
| User entered 'None (0)' | System | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:34', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' | System | 25 Sep 2020 00:49:56 |
| User entered 'None (0)' | System | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' | System | 25 Sep 2020 00:49:56 |
| User entered 'None (0)' | System | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' | System | 25 Sep 2020 00:49:56 |
| User entered 'None (0)' | System | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' | System | 25 Sep 2020 00:49:56 |
| User entered 'None (0)' | System | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:51', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' | System | 25 Sep 2020 00:49:56 |
| User entered 'No (N)' | System | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' | System | 25 Sep 2020 00:49:56 |
| User entered '24 Sep 2020 19:49' | System | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 13:44' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 2' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:33:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' | System | 25 Sep 2020 23:34:39 |
| User entered 'None (0)' | System | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:34:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' | System | 25 Sep 2020 23:34:39 |
| User entered 'None (0)' | System | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:33:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' | System | 25 Sep 2020 23:34:39 |
| User entered 'None (0)' | System | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:33:27', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' | System | 25 Sep 2020 23:34:39 |
| User entered 'None (0)' | System | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:33:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' | System | 25 Sep 2020 23:34:39 |
| User entered 'Some interference with activity or >2 episodes/24 hours (2)' | System | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:33:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' | System | 25 Sep 2020 23:34:39 |
| User entered 'Some interference with activity not requiring medical attention (2)' | System | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:34:01', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' | System | 25 Sep 2020 23:34:39 |
| User entered 'No (N)' | System | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:34:34', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' | System | 25 Sep 2020 23:34:39 |
| User entered '25 Sep 2020 18:34' | System | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 3' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' | System | 27 Sep 2020 16:07:35 |
| User entered 'None (0)' | System | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' | System | 27 Sep 2020 16:07:35 |
| User entered 'None (0)' | System | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' | System | 27 Sep 2020 16:07:35 |
| User entered 'None (0)' | System | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' | System | 27 Sep 2020 16:07:35 |
| User entered 'None (0)' | System | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' | System | 27 Sep 2020 16:07:35 |
| User entered 'None (0)' | System | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' | System | 27 Sep 2020 16:07:35 |
| User entered 'None (0)' | System | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:30', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' | System | 27 Sep 2020 16:07:35 |
| User entered 'No (N)' | System | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' | System | 27 Sep 2020 16:07:35 |
| User entered '27 Sep 2020 11:07' | System | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 4' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' | System | 28 Sep 2020 01:13:05 |
| User entered 'None (0)' | System | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:50', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' | System | 28 Sep 2020 01:13:05 |
| User entered 'None (0)' | System | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' | System | 28 Sep 2020 01:13:05 |
| User entered 'None (0)' | System | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' | System | 28 Sep 2020 01:13:05 |
| User entered 'None (0)' | System | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:56', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' | System | 28 Sep 2020 01:13:05 |
| User entered 'None (0)' | System | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:58', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' | System | 28 Sep 2020 01:13:05 |
| User entered 'None (0)' | System | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:13:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' | System | 28 Sep 2020 01:13:05 |
| User entered 'No (N)' | System | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:13:02', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' | System | 28 Sep 2020 01:13:05 |
| User entered '27 Sep 2020 20:13' | System | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 5' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System | 29 Sep 2020 00:00:38 |
| User entered 'None (0)' | System | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System | 29 Sep 2020 00:00:38 |
| User entered 'None (0)' | System | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:20', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System | 29 Sep 2020 00:00:38 |
| User entered 'None (0)' | System | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:22', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System | 29 Sep 2020 00:00:38 |
| User entered 'None (0)' | System | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System | 29 Sep 2020 00:00:38 |
| User entered 'None (0)' | System | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System | 29 Sep 2020 00:00:38 |
| User entered 'None (0)' | System | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:31', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System | 29 Sep 2020 00:00:38 |
| User entered 'No (N)' | System | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System | 29 Sep 2020 00:00:38 |
| User entered '28 Sep 2020 19:00' | System | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 6' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' | System | 30 Sep 2020 12:02:10 |
| User entered 'None (0)' | System | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' | System | 30 Sep 2020 12:02:10 |
| User entered 'None (0)' | System | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' | System | 30 Sep 2020 12:02:10 |
| User entered 'None (0)' | System | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' | System | 30 Sep 2020 12:02:10 |
| User entered 'None (0)' | System | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' | System | 30 Sep 2020 12:02:10 |
| User entered 'None (0)' | System | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' | System | 30 Sep 2020 12:02:10 |
| User entered 'None (0)' | System | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:02:04', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' | System | 30 Sep 2020 12:02:10 |
| User entered 'No (N)' | System | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:02:06', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' User entered '30 Sep 2020 07:02' | System | 30 Sep 2020 12:02:10 |
| | System | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:05:06 |
| User entered 'Day 7' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:23', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' | System | 01 Oct 2020 12:02:45 |
| User entered 'None (0)' | System | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' | System | 01 Oct 2020 12:02:45 |
| User entered 'None (0)' | System | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' | System | 01 Oct 2020 12:02:45 |
| User entered 'None (0)' | System | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:31', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' | System | 01 Oct 2020 12:02:45 |
| User entered 'None (0)' | System | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' | System | 01 Oct 2020 12:02:45 |
| User entered 'None (0)' | System | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' | System | 01 Oct 2020 12:02:45 |
| User entered 'None (0)' | System | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' | System | 01 Oct 2020 12:02:45 |
| User entered 'No (N)' | System | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' | System | 01 Oct 2020 12:02:45 |
| User entered '01 Oct 2020 07:02' | System | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 12:00' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 24 Sep 2020 15:05:06 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 01 Oct 2020 18:46:22 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| User entered '1 Oct 2020' | (b) (4), (b) (6) | 01 Oct 2020 18:46:22 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 01 Oct 2020 18:46:22 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 01 Oct 2020 18:46:22 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 01 Oct 2020 18:46:32 |
| | | |

US3292324

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 01 Oct 2020 18:46:32 |

US3292324

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 08 Oct 2020 15:09:40 |

US3292324

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User entered '8 Oct 2020' | Kristy Trevino (b) (4) (b) (4) | 08 Oct 2020 15:09:40 |

US3292324

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 08 Oct 2020 15:09:40 |

US3292324

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 08 Oct 2020 15:09:40 |

US3292324

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 08 Oct 2020 15:09:49 |

US3292324

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 08 Oct 2020 15:09:49 |

US3292324

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 15 Oct 2020 20:50:16 |

US3292324

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '15 Oct 2020' | Kristy Trevino (b) (4) (b) (4) | 15 Oct 2020 20:50:16 |

US3292324

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) (b) (4) | 15 Oct 2020 20:50:16 |

US3292324

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 15 Oct 2020 20:50:16 |

US3292324

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) (b) (4) | 15 Oct 2020 20:50:21 |

US3292324

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 15 Oct 2020 20:50:21 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:40:28 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '22 Oct 2020' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:40:28 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:40:28 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:07

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 22 Oct 2020 15:40:28 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

Were vital signs assessed?

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '22 Oct 2020' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| User entered '09:12' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 09:12' | System | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered '37.1' C | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (Oral)' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '75' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '12' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|---------------------------------|----------------------|
| User entered '123' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|---------------------------------|----------------------|
| User entered '75' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:07

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:07

Was the physical examination performed?

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:26 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:07

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:26 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

Was the sample collected?

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:44 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '22 Oct 2020' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:44 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|---------------------------------|----------------------|
| User entered '09:22' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:44 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:07

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 09:22' | System | 22 Oct 2020 15:41:44 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 22 Oct 2020 15:41:48 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Oct 2020 15:41:48 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 64' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-27T07:43:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10ea2bb9-63ac-40fe-b03a-84aa6fd144f2' | System | 27 Oct 2020 12:43:48 |
| User entered 'No (N)' | System | 27 Oct 2020 12:43:48 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-27T07:43:37', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10ea2bb9-63ac-40fe-b03a-84aa6fd144f2' | System | 27 Oct 2020 12:43:48 |
| User entered 'No (N)' | System | 27 Oct 2020 12:43:48 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-27T07:43:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10ea2bb9-63ac-40fe-b03a-84aa6fd144f2' | System | 27 Oct 2020 12:43:48 |
| User entered '27 Oct 2020 07:43:45' | System | 27 Oct 2020 12:43:48 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered '27 Oct 2020 00:01' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered '31 Oct 2020 23:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 71' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:52:50', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdcbb19b57' | System | 05 Nov 2020 01:53:51 |
| User entered 'Yes (Y)' | System | 05 Nov 2020 01:53:51 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:52:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdc19b57' | System | 05 Nov 2020 01:53:51 |
| User entered 'No (N)' | System | 05 Nov 2020 01:53:51 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:53:02', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdcdb19b57' | System | 05 Nov 2020 01:53:51 |
| User entered 'No (N)' | System | 05 Nov 2020 01:53:51 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:53:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdc19b57' | System | 05 Nov 2020 01:53:51 |
| User entered 'Yes (Y)' | System | 05 Nov 2020 01:53:51 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:53:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdc19b57' | System | 05 Nov 2020 01:53:51 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 05 Nov 2020 01:53:51 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:53:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdcdb19b57' | System | 05 Nov 2020 01:53:51 |
| User entered '04 Nov 2020 19:53:42' | System | 05 Nov 2020 01:53:51 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered '03 Nov 2020 00:01' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered '07 Nov 2020 23:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered 'Day 78' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' | System | 11 Nov 2020 18:05:02 |
| User entered 'Yes (Y)' | System | 11 Nov 2020 18:05:02 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:30', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' | System | 11 Nov 2020 18:05:02 |
| User entered 'No (N)' | System | 11 Nov 2020 18:05:02 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' | System | 11 Nov 2020 18:05:02 |
| User entered 'No (N)' | System | 11 Nov 2020 18:05:02 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' | System | 11 Nov 2020 18:05:02 |
| User entered 'Yes (Y)' | System | 11 Nov 2020 18:05:02 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' | System | 11 Nov 2020 18:05:02 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 11 Nov 2020 18:05:02 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' User entered '11 Nov 2020 12:04:48' | System | 11 Nov 2020 18:05:02 |
| | System | 11 Nov 2020 18:05:02 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered '10 Nov 2020 00:01' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 27 Aug 2020 15:43:21 |
| User entered '14 Nov 2020 23:59' | System | 27 Aug 2020 15:43:21 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Oct 2020 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 Oct 2020 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '31 Oct 2020 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '04 Nov 2020 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '07 Nov 2020 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '11 Nov 2020 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '14 Nov 2020 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '18 Nov 2020 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-21T03:28:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '88269b42-7908-4c24-922a-e97f989b9cb0' User entered 'No (N)' | System | 21 Nov 2020 09:28:44 |
| | System | 21 Nov 2020 09:28:44 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-21T03:28:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '88269b42-7908-4c24-922a-e97f989b9cb0' | System | 21 Nov 2020 09:28:44 |
| User entered 'No (N)' | System | 21 Nov 2020 09:28:44 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-21T03:28:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '88269b42-7908-4c24-922a-e97f989b9cb0' User entered '21 Nov 2020 03:28:42' | System | 21 Nov 2020 09:28:44 |
| | System | 21 Nov 2020 09:28:44 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '15 Oct 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 Oct 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 Oct 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 Oct 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 Oct 2022 00:01' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Nov 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 19:29:09 |

US3292324

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User entered '19 Nov 2020' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 19:29:09 |

US3292324

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 19:29:09 |

US3292324

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 19:29:09 |

US3292324

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Gerardo Pena (b) (4) (b) (4) | 23 Nov 2020 19:29:13 |

US3292324

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 23 Nov 2020 19:29:13 |

US3292324

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:53:07

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) (b) (4) | 24 Sep 2020 17:15:28 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:01 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Sep 2020 17:17:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Sep 2020 17:17:54 |
| Data point term sent to Coder | System | 24 Sep 2020 17:17:09 |
| User entered 'urinary tract infection' | Kevin Martinez (b) (4) (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:02 |
| User entered 'No (N)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:03 |
| User entered 'No (N)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:06 |
| User entered 'No (N)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:08 |
| User entered '16 Sep 2020' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |
| | (b) (4) | |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:09 |
| User entered empty. | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:11 |
| User entered 'No (N)' reason for change: Data Entry Error | Dawn Killian (b) (4) | 04 Nov 2020 19:03:51 |
| User entered 'Yes (Y)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:12 |
| User entered '26 Sep 2020' reason for change: Data Entry Error | Darlington Akahara (b) (4) | 06 Nov 2020 21:58:33 |
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | System | 04 Nov 2020 19:04:37 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System | 04 Nov 2020 19:04:37 |
| User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System). | System | 04 Nov 2020 19:04:37 |
| User entered '16 Sep 2020' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 04 Nov 2020 19:04:37 |
| User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System). | System | 04 Nov 2020 19:03:51 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | System | 04 Nov 2020 19:03:51 |
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:13 |
| User entered empty. | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |
| | (b) (4) | |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:15 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |
| | (b) (4) | |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:16 |
| User entered 'No (N)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:18 |
| User entered '0' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:19 |
| User entered '0' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:21 |
| User entered '0' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:22 |
| User entered empty. | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:23 |
| User entered empty. | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:25 |
| User entered empty. | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |
| | (b) (4) | |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:26 |
| User entered empty. | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |
| | (b) (4) | |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:28 |
| User entered '0' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:29 |
| User entered '0' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:30 |
| User entered '0' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:32 |
| User entered 'Not Related (NOT RELATED)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:33 |
| User entered 'Not Related (NOT RELATED)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:35 |
| User entered 'None (NONE)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[None](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 23:46:58 |
| | (b) (4), (b) (6) | 23 Nov 2020 17:52:36 |
| User entered 'I' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |
| | (b) (4) | |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:37 |
| User entered '0' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:39 |
| User entered '0' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |
| | (b) (4) | |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:40 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Dawn Killian (b) (4) (b) (4) | 04 Nov 2020 19:03:51 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Kevin Martinez (b) (4) (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:41 |
| User entered empty. | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:52:43 |
| User entered empty. | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:16 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:02 |
| User entered 'USA-US072-2020-mRNA-1273-P301000008' | System | 04 Nov 2020 18:48:49 |
| User entered 'New' | (b) (4), (b) (6) | 04 Nov 2020 18:48:49 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:17 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femur fracture, LLT: Fracture femur - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Nov 2020 15:05:24 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 04 Nov 2020 15:05:24 |
| Data point term sent to Coder | System | 04 Nov 2020 14:44:49 |
| User entered 'R broken femur' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:18 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:20 |
| User entered 'No (N)' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:21 |
| User entered 'No (N)' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:23 |
| User entered '3 Nov 2020' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:24 |
| User entered empty. | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:26 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:30 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 16:31:55 |
| | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:32 |
| User entered empty. | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User closed query 'PV Query: As the event resulted in hospitalization, please confirm the intensity of grade 3.' (Site from Safety). | (b) (4), (b) (6) | 24 Nov 2020 17:10:36 |
| Query 'PV Query: As the event resulted in hospitalization, please confirm the intensity of grade 3.' answered with 'confirmed' (Site from Safety). | Gerardo Pena (b) (4) | 23 Nov 2020 19:29:56 |
| User opened query 'PV Query: As the event resulted in hospitalization, please confirm the intensity of grade 3.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:32:10 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:37 |
| User entered '0' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:38 |
| User entered '0' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:40 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 23 Nov 2020 15:39:54 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still admitted.' (Site from System). | (b) (4), (b) (6) | 04 Nov 2020 14:45:30 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 04 Nov 2020 14:43:56 |
| User entered '1' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:42 |
| User entered '3 Nov 2020' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:54:47 |
| User opened query 'PV Query: Please provide hospital discharge date when available.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:31:46 |
| User entered empty. | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:57:03 |
| User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). | System | 04 Nov 2020 14:45:41 |
| Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System). | | 04 Nov 2020 14:45:41 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 14:45:41 |
| User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). | System | 04 Nov 2020 14:43:56 |
| User entered 'Unknown (UNK)' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:57:05 |
| User entered empty. | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:57:06 |
| User entered '0' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:57:08 |
| User entered '0' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:57:09 |
| User entered '0' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:57:10 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:57:12 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:57:13 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Antonio Gutierrez (b) (4) | 04 Nov 2020 15:21:39 |
| reason for change: Data Entry Error | | |
| User entered 'None (NONE)' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |
| | | |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[None](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:57:16 |
| User entered '0' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:56:59 |
| User entered '0' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per Narrative, Patient was taken to the OR for Surgery for Repair. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 23:47:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:56:57 |
| Query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' canceled (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 15:39:59 |
| User opened query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 14 Nov 2020 22:47:14 |
| User entered 'I' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:56:55 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:31:36 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:56:50 |
| User entered empty. | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 17:56:53 |
| User opened query 'PV Query: Please confirm if the fall was a mechanical fall or if the subject experienced dizziness/lightheadedness/etc.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:32:31 |
| User opened query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:32:27 |
| User opened query 'PV Query: Please provide treatment for the event (including name/date of surgical procedure) and any treatment medications. Please add treatment medications to CM eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:32:17 |
| User opened query 'PV Query: Please provide the results of any imaging performed related to the event.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:32:03 |
| User opened query 'PV Query: Is shingles considered med history (prior to start of study)? If so, please add to MH eCRF.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 16:31:30 |
| User entered 'SUBJECT CALLED TO INFORM US sHE IS CURRENTLY ADMITTED AT METROPOLITAN METHODIST FOR A BROKEN FEMUR. SHE STATES SHE BROKE HER FEMUR YESTERDAY(03-NOV-2020) DURING A FALL PICKING UP HER GROCERIES. SHE WENT TO THE ER (AT HOSPITAL STATED ABOVE) AND WAS TAKEN TO THE OR FOR SURGERY FOR REPAIR. SHE IS CURRENTLY STAYING FOR OBSERVATION AND IS EXPECTED TO STAY FOR ABOUT 3-4 DAYS. RECORDS WILL BE REQUESTED.' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 14:46:19 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered 'Subject called to inform us he is currently admitted at Metropolitan Methodist for a broken femur. She states she broke her femur yesterday(03-Nov-2020) during a fall picking up her groceries. She went to the ER (at hospital stated above) and was taken to the OR for surgery for repair. She is currently staying for observation and is expected to stay for about 3-4 days. Records will be requested.' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:53:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 04 Nov 2020 14:43:56 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:53:07

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User closed query 'Per CDM: Please update medication used for dairy dose 2 day 2' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 12:20:34 |
| Query 'Per CDM: Please update medication used for dairy dose 2 day 2' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 08 Oct 2020 19:37:54 |
| User opened query 'Per CDM: Please update medication used for dairy dose 2 day 2' (Site from DM). | (b) (4), (b) (6) | 29 Sep 2020 11:56:57 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:11:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 02 Oct 2020 18:58:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 02 Oct 2020 18:58:47 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE, PRODUCTSYNONYM: CENTRUM SILVER [ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 15 Sep 2020 17:30:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 15 Sep 2020 17:30:47 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

Name of Medication

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Sep 2020 14:14:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Sep 2020 14:14:48 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM;CHLORINE;CHROMIUM;COPPER;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FOLIC ACID;IODINE;MAGNESIUM;MANGANESE;MOLYBDENUM;NICKEL;NICOTINAMIDE;PANTOTHENIC ACID;PHOSPHORUS;PHYTOMENADIONE;POTASSIUM;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;SILICON;THIAMINE;VANADIUM;VITAMIN D NOS;XANTOFYL;ZINC, PRODUCTSYNONYM: CENTRUM SILVER +50 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 13:13:41 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 13:13:41 |
| Data point term sent to Coder | System | 28 Aug 2020 13:12:19 |
| User entered 'centrum silver' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 13:11:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------|----------------------|
| User entered 'nutritional supplement' | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '1' | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'tablet (TABLET)' | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2010' | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:11:39 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 28 Aug 2020 13:11:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 28 Aug 2020 13:11:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 28 Aug 2020 13:11:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 13:23:41 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 13:23:41 |
| Data point term sent to Coder | System | 28 Aug 2020 13:22:35 |
| User entered 'B12' reason for change: Data Entry Error | (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) | 28 Aug 2020 13:22:10 |
| Data point term sent to Coder | System | 28 Aug 2020 13:13:24 |
| User entered 'Biz' | (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------|----------------------|
| User entered 'nutritional supplement' | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'unknown' (Site from DM). | Dawn Killian (b) (4) (b) (4) | 24 Sep 2020 01:05:54 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) (b) (4) | 22 Sep 2020 11:12:10 |
| User entered 'I' | (b) (4), (b) (6) (b) (4) (b) (4) | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'tablet (TABLET)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2015' | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:00 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 13:15:40 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 13:15:40 |
| Data point term sent to Coder | System | 28 Aug 2020 13:14:25 |
| User entered 'biotin' | (b) (4), (b) (6) (b) (4) | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------|----------------------|
| User entered 'nutritional supplement' | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered '5000' | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. Otherwise, confirm if the unit should be updated to 'ug'. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4) | 24 Sep 2020 01:06:42 |
| User entered 'ug (ug)' reason for change: Data Entry Error | (b) (4) | 24 Sep 2020 01:06:36 |
| User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. Otherwise, confirm if the unit should be updated to 'ug'. ' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 11:16:47 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '20 Aug 2020' | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:13:31 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 28 Aug 2020 13:15:40 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 28 Aug 2020 13:15:40 |
| Data point term sent to Coder | System | 28 Aug 2020 13:14:25 |
| User entered 'synthroid' | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------|----------------------|
| User entered 'thyroid cancer' | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '200' | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'ug (ug)' | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2014' | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Aug 2020 13:14:01 |
| | | |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 28 Aug 2020 13:14:01 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 28 Aug 2020 13:14:01 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 28 Aug 2020 13:14:01 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Oct 2020 18:50:52 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Oct 2020 18:50:52 |
| Data point term sent to Coder | System | 01 Oct 2020 18:49:40 |
| User entered 'Tylenol' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| User entered 'Fever/pain' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '500' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '25 Sep 2020' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |
| | | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '25 Sep 2020' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: INTERMEDIATE-ACTING SULFONAMIDES, PRODUCT: SULFAMETHOXAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 09 Oct 2020 20:18:58 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 09 Oct 2020 20:18:58 |
| Data point term sent to Coder | System | 09 Oct 2020 01:51:32 |
| User entered 'sulfamethoxazole' | Kristy Trevino (b) (4) | 09 Oct 2020 01:50:39 |
| | (b) (4) | |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Urinary tract Infection' | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|-----------------------------------|----------------------|
| User entered 'UNK' | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------------|----------------------|
| User entered 'Other (OTHER)' | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User entered 'Subject bottle does not state dose' | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User entered 'twice daily (BID)' | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Sep 2020' | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Kevin Martinez (b) (4) | 22 Oct 2020 15:53:02 |
| User entered 'Yes (Y)' | Kristy Trevino (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User entered '26 Sep 2020' reason for change: Data Entry Error | Kevin Martinez (b) (4) | 22 Oct 2020 15:53:02 |
| User entered empty. | Kristy Trevino (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kristy Trevino (b) (4) (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 15:55:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 15:55:35 |
| Data point term sent to Coder | System | 22 Oct 2020 15:54:31 |
| User entered 'acyclovir' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------|-----------------------------------|----------------------|
| User entered 'Shingles' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|-----------------------------------|----------------------|
| User entered '400' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User entered 'twice daily (BID)' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '14 Sep 2020' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '24 Sep 2020' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Kevin Martinez (b) (4) (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:53:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Oct 2020 15:54:28 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'USA-US072-2020-MRNA-1273-P301000008' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Douglas' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Denham' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '7940 Floyd Curl Drive' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'San Antonio' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '78229' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Investigator Country](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered 'US' | System | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'USA-US072-2020-MRNA-1273-P301000008' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Douglas' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Denham' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '7940 Floyd Curl Drive' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'San Antonio' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '78229' | System | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[Investigator Country](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered 'US' | System | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:53:07

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '04/Nov/2020 18:49' | System | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:53:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered 'I' | (b) (4), (b) (6) | 04 Nov 2020 18:49:26 |