

US3452332 (Prod: Lynn Health Science Institute)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:49:36

All time stamps listed in this document are displayed in GMT

US3452332

Form: Participant Creation

Data signed: (b) (4) 17 Apr 2021 15:12:57

Generated On: 11 Aug 2021 22:49:36

Participant ID

US3452332

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

US3452332

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 07 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

US3452332

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1955 |
| Age | 65 |
| Age Units | YEARS |
| Age (Derived) | 65 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" 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

Data signed: (b) (4) 17 Feb 2021 18:25:38

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 18:25:38

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 18:25:38

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 18:25:38

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| | |
|---|--|
| Condition | SEASONAL ALLERGIES |
| Start date (dd MMM yyyy) | UN UNK 2001 |
| 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 2001 |
| Start Year (derived) | 2001 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 18:25:38

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| | |
|---|--|
| Condition | GERD |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| 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 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Condition | HIGH CHOLESTEROL |
| 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 (4)

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Condition | DIABETES TYPE II |
| Start date (dd MMM yyyy) | UN JUN 2019 |
| 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) | JUN 2019 |
| Start Year (derived) | 2019 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Condition | EDEMA BOTH FEET |
| Start date (dd MMM yyyy) | UN UNK 1995 |
| 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 1995 |
| Start Year (derived) | 1995 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Condition | HEADACHES |
| Start date (dd MMM yyyy) | UN UNK 1985 |
| 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 1985 |
| Start Year (derived) | 1985 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 18:25:38

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| | |
|---|--|
| Condition | VASECTOMY |
| Start date (dd MMM yyyy) | UN UNK 1997 |
| 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 1997 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1997 |
| Start Year (derived) | 1997 |
| Stop Month and Year (derived) | JAN 1997 |
| Stop Year (derived) | 1997 |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Condition | HEART ATTACK |
| Start date (dd MMM yyyy) | UN UNK 1995 |
| 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 1995 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1995 |
| Start Year (derived) | 1995 |
| Stop Month and Year (derived) | JAN 1995 |
| Stop Year (derived) | 1995 |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN UNK 1995 |
| 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 1995 |
| Start Year (derived) | 1995 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 17 Feb 2021 18:25:38

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| | |
|---|--|
| Condition | ANXIETY |
| Start date (dd MMM yyyy) | UN UNK 2005 |
| 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 2005 |
| Start Year (derived) | 2005 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 17 Feb 2021 18:25:38

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| | |
|---|--|
| Condition | DISC REPAIR OF BACK |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| 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 2016 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | JAN 2016 |
| Stop Year (derived) | 2016 |

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Condition | ALLERGY TO PENICILLIN |
| Start date (dd MMM yyyy) | UN UNK 1995 |
| 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 1995 |
| Start Year (derived) | 1995 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Condition | BACK PAIN |
| Start date (dd MMM yyyy) | UN UNK 2015 |
| 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 2015 |
| Start Year (derived) | 2015 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 07 AUG 2020 |
| Time of assessment (00:00-23:59) | 15:06 (24 HR) |
| Vital Signs Date and Time (derived) | 07 AUG 2020 15:06 |
| Height (xxx.x) | 69.2 in |
| Weight (xxx.x) | 221.8 lb |
| BMI (xxx.x) | 32.63317 kg/m ² |
| BMI units | KG/M2 |
| Temperature (xxx.x) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (xxx) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 18:25:39

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

TRUCK DRIVER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 18:25:39

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 07 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

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

What was the participant's randomization number? 185244

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------------------------------|--|
| 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) | 07 AUG 2020 |
| Time of assessment (00:00-23:59) | 15:06 (24 HR) |
| Vital Signs Date and Time (derived) | 07 AUG 2020 15:06 |
| Temperature (xxx.x) | 98.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 61 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 140 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 81 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------------------------------|--|
| 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) | 07 AUG 2020 |
| Time of assessment (00:00-23:59) | 16:13 (24 HR) |
| Vital Signs Date and Time (derived) | 07 AUG 2020 16:13 |
| Temperature (xxx.x) | 98.3 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 63 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 131 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 77 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:38 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 15:38

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 07 AUG 2020 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 15:25 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 07 AUG 2020 15:25 |
|------------------------------------|-------------------|

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 07 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 15:29 | 07 AUG 2020 15:29 |
| Nasopharyngeal Swab 2 | Yes | 15:29 | 07 AUG 2020 15:29 |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

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: 11 Aug 2021 22:49:36

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 16:11

PC Open Date & Time

07 AUG 2020 15:58

PC Close Date & Time

07 AUG 2020 18:28

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

96.5 °F

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

Yes ☐
No ☒

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 07 AUG 2020 19:27 |
| PC Open Date & Time | 07 AUG 2020 19:23 |
| PC Close Date & Time | 08 AUG 2020 11:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 12:03

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

97.8 °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

09 AUG 2020 12:04

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

10 AUG 2020 12:04

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 12:24

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

12 AUG 2020 12:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:51

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 16:11

PC Open Date & Time

07 AUG 2020 15:58

PC Close Date & Time

07 AUG 2020 18:28

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 19:28

PC Open Date & Time

07 AUG 2020 19:23

PC Close Date & Time

08 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 12:04

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 12:05

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 12:04

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 12:24

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:51

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 07 AUG 2020 16:12 |
| PC Open Date & Time | 07 AUG 2020 15:58 |
| PC Close Date & Time | 07 AUG 2020 18:28 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 07 AUG 2020 19:30 |
| PC Open Date & Time | 07 AUG 2020 19:23 |
| PC Close Date & Time | 08 AUG 2020 11:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

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 ☒

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 AUG 2020 12:07 |
| PC Open Date & Time | 08 AUG 2020 12:00 |
| PC Close Date & Time | 09 AUG 2020 11:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 AUG 2020 12:06 |
| PC Open Date & Time | 09 AUG 2020 12:00 |
| PC Close Date & Time | 10 AUG 2020 11:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

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 ☒

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 AUG 2020 12:05 |
| PC Open Date & Time | 10 AUG 2020 12:00 |
| PC Close Date & Time | 11 AUG 2020 11:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

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 ☒

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

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

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

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

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 13 AUG 2020 12:52 |
| PC Open Date & Time | 13 AUG 2020 12:00 |
| PC Close Date & Time | 14 AUG 2020 11:59 |

US3452332

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 03 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 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------------------------------|---|
| 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) | 03 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:17 (24 HR) |
| Vital Signs Date and Time (derived) | 03 SEP 2020 11:17 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 63 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 138 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 85 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 03 SEP 2020 |
| Time of assessment (00:00-23:59) | 12:24 (24 HR) |
| Vital Signs Date and Time (derived) | 03 SEP 2020 12:24 |
| Temperature (xxx.x) | 98.3 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 69 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 134 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3452332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 03 SEP 2020

What was the treatment time? (00:00-23:59) 11:45 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 11:45

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

What was the frequency of the study treatment dosing? ONCE

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

US3452332

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 SEP 2020

Collection time (00:00-23:59)

11:24 (24 HR)

Collection date and time (derived)

03 SEP 2020 11:24

US3452332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

| Collection date (dd MMM yyyy) | | | 03 SEP 2020 |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:26 | 03 SEP 2020 11:26 |
| Nasopharyngeal Swab 2 | Yes | 11:26 | 03 SEP 2020 11:26 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:22

PC Open Date & Time

03 SEP 2020 12:05

PC Close Date & Time

03 SEP 2020 14:35

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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 96.8 °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 | 04 SEP 2020 06:30 |
| PC Open Date & Time | 03 SEP 2020 15:30 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 17:52

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 15:29

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 12:08

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:41

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:02

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

09 SEP 2020 12:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

03 SEP 2020 12:23

PC Open Date & Time

03 SEP 2020 12:05

PC Close Date & Time

03 SEP 2020 14:35

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

04 SEP 2020 06:31

PC Open Date & Time

03 SEP 2020 15:30

PC Close Date & Time

04 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

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

04 SEP 2020 17:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

05 SEP 2020 15:29

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

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

06 SEP 2020 12:08

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

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

07 SEP 2020 12:42

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

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

08 SEP 2020 12:03

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 03 SEP 2020 12:23 |
| PC Open Date & Time | 03 SEP 2020 12:05 |
| PC Close Date & Time | 03 SEP 2020 14:35 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 04 SEP 2020 06:34 |
| PC Open Date & Time | 03 SEP 2020 15:30 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

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 ☒

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 SEP 2020 17:54 |
| PC Open Date & Time | 04 SEP 2020 12:00 |
| PC Close Date & Time | 05 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 3857

EAB) (1725)

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 SEP 2020 15:30 |
| PC Open Date & Time | 05 SEP 2020 12:00 |
| PC Close Date & Time | 06 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

104 of 3857

EAB) (1725)

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 06 SEP 2020 12:10 |
| PC Open Date & Time | 06 SEP 2020 12:00 |
| PC Close Date & Time | 07 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

106 of 3857

EAB) (1725)

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 SEP 2020 12:43 |
| PC Open Date & Time | 07 SEP 2020 12:00 |
| PC Close Date & Time | 08 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

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 ☒

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 SEP 2020 12:04 |
| PC Open Date & Time | 08 SEP 2020 12:00 |
| PC Close Date & Time | 09 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

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 ☒

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 SEP 2020 12:03 |
| PC Open Date & Time | 09 SEP 2020 12:00 |
| PC Close Date & Time | 10 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 10 SEP 2020 12:01

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 9

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 SEP 2020 14:02

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 10

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

12 SEP 2020 12:23

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 11

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

13 SEP 2020 22:17

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 12

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

14 SEP 2020 14:30

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 13

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

15 SEP 2020 12:02

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 14

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

16 SEP 2020 12:22

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 15

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

17 SEP 2020 12:04

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 16

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

18 SEP 2020 12:12

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 17

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

19 SEP 2020 14:27

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 18

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 SEP 2020 12:16

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 19

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

21 SEP 2020 12:02

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 20

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

22 SEP 2020 12:00

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 21

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 SEP 2020 12:30

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 22

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 SEP 2020 13:25

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 23

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

25 SEP 2020 12:06

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 24

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

26 SEP 2020 14:17

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 25

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 27 SEP 2020 12:04

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 26

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

28 SEP 2020 12:28

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 27

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

29 SEP 2020 13:42

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 28

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

30 SEP 2020 13:13

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 29

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 01 OCT 2020 12:00

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 30

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 OCT 2020 12:22

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 31

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 03 OCT 2020 12:47

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 32

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

04 OCT 2020 13:14

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 33

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 05 OCT 2020 12:00

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 34

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

06 OCT 2020 12:22

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 35

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

07 OCT 2020 12:00

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 36

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 08 OCT 2020 14:01

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 37

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

09 OCT 2020 12:00

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 38

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 10 OCT 2020 12:20

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 39

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 OCT 2020 15:35

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 40

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

12 OCT 2020 12:01

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 41

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 13 OCT 2020 12:01

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 42

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 14 OCT 2020 14:40

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 43

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

15 OCT 2020 12:01

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 44

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

16 OCT 2020 13:16

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 45

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 17 OCT 2020 12:00

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 46

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

18 OCT 2020 12:28

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 47

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

19 OCT 2020 12:46

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 48

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 21 OCT 2020 08:50

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 49

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 22 OCT 2020 09:02

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 50

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

22 OCT 2020 12:48

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 51

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 52

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 8

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

| | |
|---------------|-------------------|
| PC Time stamp | 10 SEP 2020 12:01 |
|---------------|-------------------|

| | |
|---------------------|-------------------|
| PC Open Date & Time | 10 SEP 2020 12:00 |
|---------------------|-------------------|

| | |
|----------------------|-------------------|
| PC Close Date & Time | 11 SEP 2020 11:59 |
|----------------------|-------------------|

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 9

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 11 SEP 2020 14:02

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 10

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 12 SEP 2020 12:23

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 11

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 13 SEP 2020 22:17

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 12

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

14 SEP 2020 14:31

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 13

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 15 SEP 2020 12:02

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 14

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

16 SEP 2020 12:22

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 15

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

17 SEP 2020 12:04

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 16

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

18 SEP 2020 12:12

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 17

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

19 SEP 2020 14:27

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 18

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 SEP 2020 12:16

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 19

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 21 SEP 2020 12:02

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 20

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 SEP 2020 12:00

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 21

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 23 SEP 2020 12:30

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 22

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 24 SEP 2020 13:25

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 23

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 25 SEP 2020 12:07

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 24

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 26 SEP 2020 14:17

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 25

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 27 SEP 2020 12:04

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 26

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 28 SEP 2020 12:28

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 27

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 29 SEP 2020 13:42

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 28

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 30 SEP 2020 13:13

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 29

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 OCT 2020 12:00

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 30

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 02 OCT 2020 12:23

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 31

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 03 OCT 2020 12:47

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 32

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 04 OCT 2020 13:14

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 33

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 05 OCT 2020 12:00

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 34

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 06 OCT 2020 12:22

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 35

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 07 OCT 2020 12:00

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 36

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 08 OCT 2020 14:01

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 37

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 09 OCT 2020 12:00

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 38

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 10 OCT 2020 12:20

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 39

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 11 OCT 2020 15:35

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 40

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 12 OCT 2020 12:01

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 41

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 13 OCT 2020 12:01

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 42

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 14 OCT 2020 14:40

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 43

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 15 OCT 2020 12:01

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 44

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 16 OCT 2020 13:16

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 45

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 OCT 2020 12:01

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 46

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 OCT 2020 12:28

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 47

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 19 OCT 2020 12:46

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 48

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 21 OCT 2020 08:50

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 49

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 OCT 2020 09:03

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 50

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 OCT 2020 12:48

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 51

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

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 52

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

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 10 SEP 2020 12:01 |
| PC Open Date & Time | 10 SEP 2020 12:00 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 11 SEP 2020 14:02 |
| PC Open Date & Time | 11 SEP 2020 12:00 |
| PC Close Date & Time | 12 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 10 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 12 SEP 2020 12:24 |
| PC Open Date & Time | 12 SEP 2020 12:00 |
| PC Close Date & Time | 13 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 11 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 13 SEP 2020 22:17 |
| PC Open Date & Time | 13 SEP 2020 12:00 |
| PC Close Date & Time | 14 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 12 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 14 SEP 2020 14:31 |
| PC Open Date & Time | 14 SEP 2020 12:00 |
| PC Close Date & Time | 15 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 13 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| PC Time stamp | 15 SEP 2020 12:02 |
| PC Open Date & Time | 15 SEP 2020 12:00 |
| PC Close Date & Time | 16 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 14 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> Yes <input checked="" type="checkbox"/> |
| PC Time stamp | 16 SEP 2020 12:22 |
| PC Open Date & Time | 16 SEP 2020 12:00 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 15 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 17 SEP 2020 12:04 |
| PC Open Date & Time | 17 SEP 2020 12:00 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 16 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 18 SEP 2020 12:12 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 17

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

No ☒

Yes ☐

PC Time stamp

19 SEP 2020 14:28

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 18 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 20 SEP 2020 12:16 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 19 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 21 SEP 2020 12:02 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 20 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 22 SEP 2020 12:01 |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 21 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 23 SEP 2020 12:30 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 22

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

No ☒

Yes ☐

PC Time stamp

24 SEP 2020 13:25

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 23

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

No ☒

Yes ☐

PC Time stamp

25 SEP 2020 12:07

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 24 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 26 SEP 2020 14:17 |
| PC Open Date & Time | 26 SEP 2020 12:00 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 25 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 27 SEP 2020 12:04 |
| PC Open Date & Time | 27 SEP 2020 12:00 |
| PC Close Date & Time | 28 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 26 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 28 SEP 2020 12:28 |
| PC Open Date & Time | 28 SEP 2020 12:00 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 27

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

No ☒

Yes ☐

PC Time stamp

29 SEP 2020 13:43

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 28

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

No ☒

Yes ☐

PC Time stamp

30 SEP 2020 13:13

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 29

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

No ☒

Yes ☐

PC Time stamp

01 OCT 2020 12:00

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 30 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 02 OCT 2020 12:23 |
| PC Open Date & Time | 02 OCT 2020 12:00 |
| PC Close Date & Time | 03 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 31

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

No ☒

Yes ☐

PC Time stamp

03 OCT 2020 12:47

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 32 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 04 OCT 2020 13:14 |
| PC Open Date & Time | 04 OCT 2020 12:00 |
| PC Close Date & Time | 05 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 33 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 05 OCT 2020 12:00 |
| PC Open Date & Time | 05 OCT 2020 12:00 |
| PC Close Date & Time | 06 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 34 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 06 OCT 2020 12:23 |
| PC Open Date & Time | 06 OCT 2020 12:00 |
| PC Close Date & Time | 07 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 35 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 07 OCT 2020 12:00 |
| PC Open Date & Time | 07 OCT 2020 12:00 |
| PC Close Date & Time | 08 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 36

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

No ☒

Yes ☐

PC Time stamp

08 OCT 2020 14:01

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 37 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 09 OCT 2020 12:00 |
| PC Open Date & Time | 09 OCT 2020 12:00 |
| PC Close Date & Time | 10 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 38 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 10 OCT 2020 12:20 |
| PC Open Date & Time | 10 OCT 2020 12:00 |
| PC Close Date & Time | 11 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 39

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

No ☒

Yes ☐

PC Time stamp

11 OCT 2020 15:35

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 40 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| PC Time stamp | 12 OCT 2020 12:01 |
| PC Open Date & Time | 12 OCT 2020 12:00 |
| PC Close Date & Time | 13 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 41 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> Yes <input checked="" type="checkbox"/> |
| PC Time stamp | 13 OCT 2020 12:02 |
| PC Open Date & Time | 13 OCT 2020 12:00 |
| PC Close Date & Time | 14 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 42 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> Yes <input checked="" type="checkbox"/> |
| PC Time stamp | 14 OCT 2020 14:42 |
| PC Open Date & Time | 14 OCT 2020 12:00 |
| PC Close Date & Time | 15 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 43 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| PC Time stamp | 15 OCT 2020 12:03 |
| PC Open Date & Time | 15 OCT 2020 12:00 |
| PC Close Date & Time | 16 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 44 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 16 OCT 2020 13:16 |
| PC Open Date & Time | 16 OCT 2020 12:00 |
| PC Close Date & Time | 17 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 45 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 17 OCT 2020 12:01 |
| PC Open Date & Time | 17 OCT 2020 12:00 |
| PC Close Date & Time | 18 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 46 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 18 OCT 2020 12:29 |
| PC Open Date & Time | 18 OCT 2020 12:00 |
| PC Close Date & Time | 19 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 47 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 19 OCT 2020 12:46 |
| PC Open Date & Time | 19 OCT 2020 12:00 |
| PC Close Date & Time | 20 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 48 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 21 OCT 2020 08:50 |
| PC Open Date & Time | 20 OCT 2020 12:00 |
| PC Close Date & Time | 21 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 49 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 22 OCT 2020 09:03 |
| PC Open Date & Time | 21 OCT 2020 12:00 |
| PC Close Date & Time | 22 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 50 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 22 OCT 2020 12:48 |
| PC Open Date & Time | 22 OCT 2020 12:00 |
| PC Close Date & Time | 23 OCT 2020 11:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 51

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 52

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3452332

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

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

US3452332

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:25:38

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 30 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3452332

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3452332

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

11:20 (24 HR)

Collection date and time (derived)

30 SEP 2020 11:20

US3452332

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:25:39

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| TIMEPOINT | DAY 64 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 07 OCT 2020 00:16:36 |
| Patient Cloud Open Date & Time | 07 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 11 OCT 2020 23:59 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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 | 14 OCT 2020 14:43:57 |
| Patient Cloud Open Date & Time | 14 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 18 OCT 2020 23:59 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☒

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 OCT 2020 08:49:20

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 92 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 04 NOV 2020 07:58:15 |
| Patient Cloud Open Date & Time | 04 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 08 NOV 2020 23:59 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 99 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 11 NOV 2020 17:53:57 |
| Patient Cloud Open Date & Time | 11 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 15 NOV 2020 23:59 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 106 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <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°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 22 NOV 2020 10:21:14 |
| Patient Cloud Open Date & Time | 22 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 26 NOV 2020 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 10:02:33

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☒

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

06 DEC 2020 10:35:27

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 16:52:47

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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 checked="" 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 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"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 20 DEC 2020 00:03:22 |
| Patient Cloud Open Date & Time | 20 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 24 DEC 2020 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 08:03:00

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 00:03:31

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 159 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 10 JAN 2021 11:10:23 |
| Patient Cloud Open Date & Time | 10 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 14 JAN 2021 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 07:37:51

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 00:02:43

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 31 JAN 2021 08:18:10 |
| Patient Cloud Open Date & Time | 31 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 04 FEB 2021 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 05:34:25

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 194 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 14 FEB 2021 03:21:43 |
| Patient Cloud Open Date & Time | 14 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 18 FEB 2021 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 08:04:07

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 07:49:58

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 04:46:56

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 222 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 14 MAR 2021 08:59:39 |
| Patient Cloud Open Date & Time | 14 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 18 MAR 2021 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 00:02:46

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 00:03:00

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 00:43:51

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 06:31:58

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

Date and time of submission

19 APR 2021 05:36:16

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☒

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

25 APR 2021 00:38:41

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 271 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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="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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 292 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 17 JUN 2021 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐
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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

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24 JUN 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 327 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 334 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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08 JUL 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 341 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 348 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

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22 JUL 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 411 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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="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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 14 OCT 2021 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 446 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 28 OCT 2021 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

US3452332

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 488 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 09 DEC 2021 23:59 |
|---|-------------------|

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 495 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 16 DEC 2021 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 30 DEC 2021 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐ 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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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17 FEB 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

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27 FEB 2022 00:01

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03 MAR 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

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10 MAR 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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17 MAR 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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20 MAR 2022 00:01

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24 MAR 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

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27 MAR 2022 00:01

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31 MAR 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 607 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

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03 APR 2022 00:01

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07 APR 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

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10 APR 2022 00:01

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14 APR 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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17 APR 2022 00:01

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21 APR 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐ 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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

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28 APR 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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05 MAY 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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 <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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 649 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 670 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 684 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 691 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01 |
| Patient Cloud Close Date & Time | 30 JUN 2022 23:59 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 705 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 712 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| TIMEPOINT | DAY 726 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐ 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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐ 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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

| 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"/> |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 06 OCT 2022 23:59 |
|---|-------------------|

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3452332

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:49:36

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 28 FEB 2021 03:13:37 |

US3452332

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 03 MAR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT4 |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3452332

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 MAR 2021

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 03 MAR 2021 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 11:54 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 03 MAR 2021 11:54 |
|------------------------------------|-------------------|

US3452332

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

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

US3452332

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | |
|--|--|
| Date of Contact | 26 OCT 2020 |
| Time of Contact | 12:45 |
| Date and Time of Contact (derived) | 26 OCT 2020 12:45 |
| Type of Contact | <div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div> |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Symptom Day

| | |
|--------|----------------------------------|
| Day 1 | <input checked="" type="radio"/> |
| Day 2 | <input type="radio"/> |
| Day 3 | <input type="radio"/> |
| Day 4 | <input type="radio"/> |
| Day 5 | <input type="radio"/> |
| Day 6 | <input type="radio"/> |
| Day 7 | <input type="radio"/> |
| Day 8 | <input type="radio"/> |
| Day 9 | <input type="radio"/> |
| Day 10 | <input type="radio"/> |
| Day 11 | <input type="radio"/> |
| Day 12 | <input type="radio"/> |
| Day 13 | <input type="radio"/> |
| Day 14 | <input type="radio"/> |
| Day 15 | <input type="radio"/> |
| Day 16 | <input type="radio"/> |
| Day 17 | <input type="radio"/> |
| Day 18 | <input type="radio"/> |
| Day 19 | <input type="radio"/> |
| Day 20 | <input type="radio"/> |
| Day 21 | <input type="radio"/> |
| Day 22 | <input type="radio"/> |
| Day 23 | <input type="radio"/> |
| Day 24 | <input type="radio"/> |
| Day 25 | <input type="radio"/> |
| Day 26 | <input type="radio"/> |
| Day 27 | <input type="radio"/> |
| Day 28 | <input type="radio"/> |
| Day 29 | <input type="radio"/> |
| Day 30 | <input type="radio"/> |
| Day 31 | <input type="radio"/> |
| Day 32 | <input type="radio"/> |

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 26 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 98.7 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input checked="" type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|----------------------|-------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 27 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 98.7 F | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input checked="" type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|----------------------|-------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 28 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 94 % | |
| O2 Saturation Units | % | |
| Temperature | 99.3 F | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input checked="" type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (4)

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 29 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 94 % | |
| O2 Saturation Units | % | |
| Temperature | 99.5 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (4)

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (5)

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input checked="" type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (5)

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| | | |
|----------------------|-------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 30 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 101.2 F | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (5)

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| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input checked="" type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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| | | |
|-----------------------------|-------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 31 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 91 % | |
| O2 Saturation Units | % | |
| Temperature | 101.2 F | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (6)

Data signed: (b) (4) 17 Apr 2021 15:13:30

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| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (7)

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input checked="" type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Data signed: (b) (4) 17 Apr 2021 15:13:30

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| | | |
|----------------------|-------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 01 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 100.4 F | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (7)

Data signed: (b) (4) 17 Apr 2021 15:13:30

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| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (8)

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input checked="" type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 02 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 99.3 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input checked="" type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 03 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 93 % | |
| O2 Saturation Units | % | |
| Temperature | 97.3 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (9)

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| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input checked="" type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 04 NOV 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 97 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 98.3 F |
|-------------|--------|

| | |
|--------|---------------------------------------|
| Chills | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|-------|---------------------------------------|
| Cough | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input checked="" type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (11)

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 05 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.6 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (11)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (11)

Data signed: (b) (4) 17 Apr 2021 15:13:30

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| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (12)

Data signed: (b) (4) 17 Apr 2021 15:13:30

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input checked="" type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (12)

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 06 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 95 % | |
| O2 Saturation Units | % | |
| Temperature | 96.2 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (13)

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input checked="" type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|------------|
| Date | 7 NOV 2020 |
|------|------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 97 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 98.4 F |
|-------------|--------|

| | |
|--------|---------------------------------------|
| Chills | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|-------|---------------------------------------|
| Cough | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (14)

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input checked="" type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (14)

Data signed: (b) (4) 17 Apr 2021 15:13:30

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| | | |
|----------------------|------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 8 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.9 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (14)

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (14)

Data signed: (b) (4) 17 Apr 2021 15:13:30

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (15)

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input checked="" type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (15)

Data signed: (b) (4) 17 Apr 2021 15:13:30

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| | | |
|----------------------|------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 9 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.8 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (15)

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Generated On: 11 Aug 2021 22:49:36

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (15)

Data signed: (b) (4) 17 Apr 2021 15:13:30

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (16)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input checked="" type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (16)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 10 NOV 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 96 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 97.0 F |
|-------------|--------|

| | |
|--------|---------------------------------------|
| Chills | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|-------|---------------------------------------|
| Cough | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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EAB) (1725)

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Form: Symptom Log (16)

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (16)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (17)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input checked="" type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (17)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 11 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 97.9 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Form: Symptom Log (17)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input checked="" type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (18)

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| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 12 NOV 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 97 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 97.9 F |
|-------------|--------|

| | | |
|--------|----------|----------------------------------|
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|-------|----------|----------------------------------|
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|---------------------|----------|----------------------------------|
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|----------------------|----------|----------------------------------|
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (18)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (19)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input checked="" type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (19)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 13 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 98.3 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (19)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (19)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (20)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input checked="" type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (20)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 14 NOV 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 98 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 98.7 F |
|-------------|--------|

| | | |
|--------|----------|----------------------------------|
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|-------|----------|----------------------------------|
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|---------------------|----------|----------------------------------|
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|----------------------|----------|----------------------------------|
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input checked="" type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 15 NOV 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 98 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 98.3 F |
|-------------|--------|

| | | |
|--------|----------|----------------------------------|
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|-------|----------|----------------------------------|
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|---------------------|----------|----------------------------------|
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|----------------------|----------|----------------------------------|
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input checked="" type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 16 NOV 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 97 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 97.9 F |
|-------------|--------|

| | |
|--------|---------------------------------------|
| Chills | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|-------|---------------------------------------|
| Cough | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (22)

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (23)

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input checked="" type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (23)

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 17 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.7 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (24)

Data signed: (b) (4) 17 Apr 2021 15:13:30

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input checked="" type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 18 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.6 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (24)

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (25)

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input checked="" type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 19 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.9 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input checked="" type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 20 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 98.1 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (27)

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input checked="" type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (27)

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 21 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.6 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (28)

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Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input checked="" type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 22 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 98.3 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (28)

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| Date of Visit | 26 OCT 2020 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of Test | 26 OCT 2020 |
| Type of Test Performed | Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 1 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 31 OCT 2020

End Date 03 NOV 2020

Oxygen Saturation 91 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Hepatic Dysfunction? Yes ☐ No ☒

Start Date

Neurologic Dysfunction? Yes ☐ No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐ No ☒

Date of Assessment

Radiographical Evidence Yes ☐ No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐ No ☒

Start Date

End Date

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| Visit | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3 | Yes | 28 OCT 2020 |
| Day 5 | No | |
| Day 7 | No | |
| Day 9 | No | |
| Day 14 | No | |
| Day 21 | No | |
| Day 28 | No | |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 26 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 | SICKD1 |
|------------|--------|

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 26 OCT 2020 |
| Time of assessment (00:00-23:59) | 13:16 (24 HR) |
| Vital Signs Date and Time (derived) | 26 OCT 2020 13:16 |
| Height (xxx.x) | 69.2 in |
| Weight (xxx.x) | 222 lb |
| Temperature (xxx.x) | 98.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 122 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 74 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3452332

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 OCT 2020

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 23 NOV 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD28 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 23 NOV 2020 |
| Time of assessment (00:00-23:59) | 10:23 (24 HR) |
| Vital Signs Date and Time (derived) | 23 NOV 2020 10:23 |
| Height (xxx.x) | 69.2 in |
| Weight (xxx.x) | 212.8 lb |
| Temperature (xxx.x) | 98.0 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 138 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 77 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Apr 2021 15:13:30

Generated On: 11 Aug 2021 22:49:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 17 Apr 2021 15:12:57

Generated On: 11 Aug 2021 22:49:36

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 NOV 2020

US3452332

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

Form: Visit Date

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 02 FEB 2021 |
|--------------------------|-------------|

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

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

US3452332

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

Form: Unblinding

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 02 FEB 2021 |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False |
| Was the participant unblinded? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Under what version of the Protocol was the Participant unblinded? | Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/> |
| Date of unblinding (<i>dd MMM yyyy</i>) | 02 FEB 2021 |
| Participant randomization assignment | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> |
| Actual Dose 1 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Actual Dose 2 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Placebo Only Flag | 1 |
| Continuing with mRNA-1273 | 1 |

US3452332

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |

US3452332

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| 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) | 02 FEB 2021 |
| Time of assessment (00:00-23:59) | 12:41 (24 HR) |
| Vital Signs Date and Time (derived) | 02 FEB 2021 12:41 |
| Temperature (xxx.x) | 98.4 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 62 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 151 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 88 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3452332

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| 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) | 02 FEB 2021 |
| Time of assessment (00:00-23:59) | 13:47 (24 HR) |
| Vital Signs Date and Time (derived) | 02 FEB 2021 13:47 |
| Temperature (xxx.x) | 98.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 87 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 154 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 87 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3452332

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

Form: Physical Examination

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 FEB 2021

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

US3452332

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

Form: Exposure

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 2 FEB 2021

What was the treatment time? (00:00-23:59) 13:14 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 13:14

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

What was the frequency of the study treatment dosing? ONCE

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

US3452332

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 02 FEB 2021 |
| Collection time (00:00-23:59) | 12:46 (24 HR) |
| Collection date and time (derived) | 02 FEB 2021 12:46 |

US3452332

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 2 FEB 2021 |
| Collection time (00:00 - 23:59) | 12:47 |
| Collection Date and Time (derived) | 2 FEB 2021 12:47 |

US3452332

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

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

| | |
|-----------------|---|
| Continuing Flag | 1 |
|-----------------|---|

| | |
|--------------------|---|
| OLD29 Placebo Flag | 1 |
|--------------------|---|

US3452332

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 03 MAR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD29 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------------------------------|---|
| 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) | 03 MAR 2021 |
| Time of assessment (00:00-23:59) | 11:43 (24 HR) |
| Vital Signs Date and Time (derived) | 03 MAR 2021 11:43 |
| Temperature (xxx.x) | 97.9 F |
| 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) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 142 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 87 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|-------------------------------------|--|
| 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) | 03 MAR 2021 |
| Time of assessment (00:00-23:59) | 13:05 (24 HR) |
| Vital Signs Date and Time (derived) | 03 MAR 2021 13:05 |
| Temperature (xxx.x) | 97.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 79 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 130 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 71 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3452332

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 MAR 2021

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

US3452332

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 03 MAR 2021

What was the treatment time? (00:00-23:59) 12:23 (24 HR)

Treatment Date and Time (derived) 03 MAR 2021 12:23

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

What was the frequency of the study treatment dosing? ONCE

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

US3452332

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452332

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 15:13:32

Generated On: 11 Aug 2021 22:49:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452332

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 08 APR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD57 |

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 APR 2021

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 08 APR 2021 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 09:16 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 08 APR 2021 09:16 |
|------------------------------------|-------------------|

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 17:22:54

Generated On: 11 Aug 2021 22:49:36

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

| | |
|--|--|
| AEID | USA-US208-2020-MRNA-1273-P30 1000005 |
| Adverse event | COVID 19 |
| 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 checked="" type="radio"/> No <input type="radio"/> |
| Start date (dd MMM yyyy) | 26 OCT 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) | 23 NOV 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"/> |

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> 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 | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

PATIENT HAD SYMPTOMS OF
COVID 19 AND CALLED IN TO
THE CENTER. PATIENT
RETURNED WITHIN 48 HOURS
FOR ILLNESS VISIT. SYMPTOMS
LISTED ON APPROPRIATE
PAGES IN SOURCE AND EDC.
PATIENT TESTED POSITIVE ON
26-OCT-2020. SUBJECT IN
CONVALESCENT PERIOD NOW.

| | |
|--|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
|--|---|

| | |
|--|---|
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
|--|---|

| | |
|--|--|
| Admitted to ICU Derived (CSA Programming Field Only) | |
|--|--|

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

AEID

Adverse event

JOINT ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

03 SEP 2020

Start time (00:00-23:59)

12:01 (24 HR)

AE start date and time (derived)

03 SEP 2020 12:01

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 OCT 2020

End time (00:00-23:59)

00:00 (24 HR)

AE End Date and Time (derived)

22 OCT 2020 00:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 03:19:05

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| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input type="radio"/> Related <input checked="" 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 <input type="radio"/> 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) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

AEID

Adverse event

MUSCLE ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

06 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input type="radio"/> Related <input checked="" 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 <input type="radio"/> 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) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 03:19:06

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2005 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HIGH BLOOD PRESSURE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 03:19:05

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2005 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 03:19:05

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2015 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | _____ | |
| Interval Dosage Unit Number (derived) | _____ | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication EDEMA BOTH FEET

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

628 of 3857

EAB) (1725)

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

| | | |
|--|--------------------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 1995 |
| 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"/> | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

Name of Medication DIGOXIN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

630 of 3857

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 03:19:05

Generated On: 11 Aug 2021 22:49:36

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 1995 | |
| 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"/> |

US3452332

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Apr 2021 15:12:57

Generated On: 11 Aug 2021 22:49:36

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3452332

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:36

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

US3452332

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:49:36

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 ☐

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|--|--|
| SAEID | USA-US208-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | |
| Investigator's Last Name | |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| SAEID | USA-US208-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | |
| Investigator's Last Name | |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 03/NOV/2020 10:26 |
| 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 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| SAEID | USA-US208-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | |
| Investigator's Last Name | |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 11/NOV/2020 13:10 |
| 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 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| SAEID | USA-US208-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | |
| Investigator's Last Name | |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 20/NOV/2020 20:26 |
| 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 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 17 Apr 2021 15:13:31

Generated On: 11 Aug 2021 22:49:36

| | |
|---|--|
| SAEID | USA-US208-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | |
| Investigator's Last Name | |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 28/DEC/2020 18:12 |
| 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

US3452332 (Prod: Lynn Health Science Institute)

US3452332

Form: Participant Creation

Generated On: 11 Aug 2021 22:49:36

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:12:57 |
| User entered 'US3452332' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 19:24:26 |

US3452332

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 19:28:10 |

US3452332

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '07 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 19:24:27 |

US3452332

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Clinic (Clinic)' | Kim Calloway (b) (4) | 07 Aug 2020 19:28:10 |

US3452332

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'SCRN' | System | 07 Aug 2020 19:28:10 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered (b) (6) 1955' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 19:24:28 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '65' | Kim Calloway (b) (4) | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'YEARS' | System | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '65' | System | 07 Aug 2020 19:28:28 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

Sex

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity samples collected for Visit 1 Day 1, Visit 2 Day 29, and Visit 3 Day 57, Female is recorded for the subject's sex, however, the CRF has Sex recorded as Male. Please clarify the subject's Sex and update if appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 13:47:44 |
| User closed query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1 and Visit 2 Day 29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 13:47:41 |
| Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity samples collected for Visit 1 Day 1, Visit 2 Day 29, and Visit 3 Day 57, Female is recorded for the subject's sex, however, the CRF has Sex recorded as Male. Please clarify the subject's Sex and update if appropriate.' answered with 'WILL CORRECT WITH LAB' (Site from DM). | April Green (b) (4) (b) (4) | 02 Nov 2020 18:03:54 |
| Query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1 and Visit 2 Day 29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you. ' answered with 'WILL CHANGE WITH LAB' (Site from DM). | April Green (b) (4) (b) (4) | 02 Nov 2020 18:03:48 |
| User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity samples collected for Visit 1 Day 1, Visit 2 Day 29, and Visit 3 Day 57, Female is recorded for the subject's sex, however, the CRF has Sex recorded as Male. Please clarify the subject's Sex and update if appropriate.' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 21:38:10 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

Sex

| Audit | User | Time (GMT) |
|--|--|--|
| User opened query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1 and Visit 2 Day 29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you. ' (Site from DM). User entered 'Male (M)' | (b) (4), (b) (6) (b) (4) Kim Calloway (b) (4) (b) (4) | 30 Oct 2020 06:50:44 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Kim Calloway (b) (4) | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

White

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'I' | Kim Calloway (b) (4) | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:36

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:38:34 |

US3452332

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:36

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '07 Aug 2020' | Kim Calloway (b) (4) | 07 Aug 2020 19:28:28 |

US3452332

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Aug 2020' | System | 07 Aug 2020 19:28:28 |

US3452332

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '2020' | System | 07 Aug 2020 19:28:28 |

US3452332

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:36

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Amendment 1 (1)' | Kim Calloway (b) (4) | 07 Aug 2020 19:28:28 |

US3452332

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 19:28:28 |

US3452332

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:36

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) Kim Calloway (b) (4) | 07 Aug 2020 19:28:28 |

US3452332

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:36

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) | |
| | Kim Calloway (b) (4) | 07 Aug 2020 19:28:28 |
| | (b) (4) | |

US3452332

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:36

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 19:28:28 |

US3452332

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:36

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 19:24:27 |

US3452332

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:36

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'I' | System | 07 Aug 2020 19:28:33 |

US3452332

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 19:28:33 |

US3452332

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:49:36

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:38:45 |

US3452332

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:36

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:40:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:40:16 |
| Data point term sent to Coder | System | 07 Aug 2020 21:39:47 |
| User entered 'SEASONAL ALLERGIES' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:11 |

US3452332

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 2001' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:11 |

US3452332

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:11 |

US3452332

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:11 |

US3452332

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 21:39:11 |

US3452332

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:11 |

US3452332

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:36

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 2001' | System | 07 Aug 2020 21:39:11 |

US3452332

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '2001' | System | 07 Aug 2020 21:39:11 |

US3452332

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:39:11 |

US3452332

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:39:11 |

US3452332

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:36

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:40:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:40:16 |
| Data point term sent to Coder | System | 07 Aug 2020 21:39:47 |
| User entered 'GERD' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:22 |

US3452332

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 2018' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:22 |

US3452332

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:22 |

US3452332

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) Kim Calloway (b) (4) | 07 Aug 2020 21:39:22 |

US3452332

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 21:39:22 |

US3452332

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:22 |

US3452332

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:36

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 2018' | System | 07 Aug 2020 21:39:22 |

US3452332

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '2018' | System | 07 Aug 2020 21:39:22 |

US3452332

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:39:22 |

US3452332

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:39:22 |

US3452332

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:36

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:40:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:40:16 |
| Data point term sent to Coder | System | 07 Aug 2020 21:39:48 |
| User entered 'HIGH CHOLESTEROL' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:43 |

US3452332

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 2010' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:43 |

US3452332

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:43 |

US3452332

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:43 |

US3452332

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 21:39:43 |

US3452332

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:39:43 |

US3452332

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:36

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 2010' | System | 07 Aug 2020 21:39:43 |

US3452332

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '2010' | System | 07 Aug 2020 21:39:43 |

US3452332

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:39:43 |

US3452332

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:39:43 |

US3452332

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:36

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| 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) | 07 Aug 2020 21:41:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:41:18 |
| Data point term sent to Coder | System | 07 Aug 2020 21:40:49 |
| User entered 'DIABETES TYPE II' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:01 |

US3452332

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN Jun 2019' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:01 |

US3452332

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:01 |

US3452332

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:01 |

US3452332

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 21:40:01 |

US3452332

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:01 |

US3452332

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:36

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jun 2019' | System | 07 Aug 2020 21:40:01 |

US3452332

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '2019' | System | 07 Aug 2020 21:40:01 |

US3452332

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:40:01 |

US3452332

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:40:01 |

US3452332

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:36

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edematous feet - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 09:52:05 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 09:52:05 |
| Data point term sent to Coder | System | 07 Aug 2020 21:40:49 |
| User entered 'EDEMA BOTH FEET' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:17 |

US3452332

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 1995' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:17 |

US3452332

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:17 |

US3452332

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:17 |

US3452332

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 21:40:17 |

US3452332

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:17 |

US3452332

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 1995' | System | 07 Aug 2020 21:40:17 |

US3452332

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '1995' | System | 07 Aug 2020 21:40:17 |

US3452332

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:40:17 |

US3452332

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:40:17 |

US3452332

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:36

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:41:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:41:18 |
| Data point term sent to Coder | System | 07 Aug 2020 21:40:51 |
| User entered 'HEADACHES' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:28 |

US3452332

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 1985' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:28 |

US3452332

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:28 |

US3452332

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:28 |

US3452332

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 21:40:28 |

US3452332

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:28 |

US3452332

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:36

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 1985' | System | 07 Aug 2020 21:40:28 |

US3452332

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:36

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '1985' | System | 07 Aug 2020 21:40:28 |

US3452332

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:40:28 |

US3452332

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:40:28 |

US3452332

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:36

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:41:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:41:18 |
| Data point term sent to Coder | System | 07 Aug 2020 21:40:49 |
| User entered 'VASECTOMY' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:46 |

US3452332

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 1997' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:46 |

US3452332

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:46 |

US3452332

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:46 |

US3452332

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 1997' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:46 |

US3452332

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:40:46 |

US3452332

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 1997' | System | 07 Aug 2020 21:40:46 |

US3452332

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '1997' | System | 07 Aug 2020 21:40:46 |

US3452332

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 1997' | System | 07 Aug 2020 21:40:46 |

US3452332

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '1997' | System | 07 Aug 2020 21:40:46 |

US3452332

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:36

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User closed query 'Per MM, please confirm the term or diagnosis' (Site from DM). | (b) (4) (b) (4), (b) (6) | 13 Oct 2020 12:15:04 |
| Query 'Per MM, please confirm the term or diagnosis' answered with 'DATA CORRECT' (Site from DM). | Kim Calloway (b) (4) | 30 Sep 2020 17:58:08 |
| User opened query 'Per MM, please confirm the term or diagnosis' (Site from DM). | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 09:13:07 |
| User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Heart attack - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 21:43:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 21:43:20 |
| Data point term sent to Coder | System | 07 Aug 2020 21:41:54 |
| User entered 'HEART ATTACK' | Kim Calloway (b) (4) (b) (4) | 07 Aug 2020 21:41:05 |

US3452332

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 1995' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:05 |

US3452332

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:05 |

US3452332

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | (b) (4) Kim Calloway (b) (4) | 07 Aug 2020 21:41:05 |

US3452332

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 1995' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:05 |

US3452332

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:05 |

US3452332

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:36

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 1995' | System | 07 Aug 2020 21:41:05 |

US3452332

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '1995' | System | 07 Aug 2020 21:41:05 |

US3452332

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 1995' | System | 07 Aug 2020 21:41:05 |

US3452332

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '1995' | System | 07 Aug 2020 21:41:05 |

US3452332

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:36

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Oct 2020 00:45:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Oct 2020 00:45:25 |
| Data point term sent to Coder | System | 15 Oct 2020 00:44:27 |
| Coding entries removed. | Kim Calloway (b) (4) | 15 Oct 2020 00:44:00 |
| User entered 'HYPERTENSION' reason for change: Data Entry Error | Kim Calloway (b) (4) | 15 Oct 2020 00:44:00 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:43:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:43:20 |
| Data point term sent to Coder | System | 07 Aug 2020 21:41:56 |
| User entered 'HIGH BLOOD PRESSURE' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:33 |

US3452332

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 1995' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:33 |

US3452332

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:33 |

US3452332

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:33 |

US3452332

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 21:41:33 |

US3452332

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:33 |

US3452332

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:36

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 1995' | System | 07 Aug 2020 21:41:33 |

US3452332

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:36

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '1995' | System | 07 Aug 2020 21:41:33 |

US3452332

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:41:33 |

US3452332

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:41:33 |

US3452332

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:36

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:43:21 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:43:21 |
| Data point term sent to Coder | System | 07 Aug 2020 21:41:54 |
| User entered 'ANXIETY' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:44 |

US3452332

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 2005' reason for change: | (b) (4) | |
| Data Entry Error | Kim Calloway (b) (4) | 19 Oct 2020 16:46:36 |
| User entered 'UN UNK 2015' | (b) (4) | |
| | Kim Calloway (b) (4) | 07 Aug 2020 21:41:44 |
| | (b) (4) | |

US3452332

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:44 |

US3452332

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:44 |

US3452332

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 21:41:44 |

US3452332

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:41:44 |

US3452332

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 2005' | System | 19 Oct 2020 16:46:36 |
| User entered 'Jan 2015' | System | 07 Aug 2020 21:41:44 |

US3452332

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '2005' | System | 19 Oct 2020 16:46:36 |
| User entered '2015' | System | 07 Aug 2020 21:41:44 |

US3452332

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:41:44 |

US3452332

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:41:44 |

US3452332

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:36

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Intervertebral disc operation - version MedDRA\23.0. | Coder Import (b) (4) | 08 Nov 2020 16:21:32 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 08 Nov 2020 16:21:32 |
| 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) | 21 Oct 2020 04:42:34 |
| Data point term sent to Coder | System | 15 Oct 2020 00:43:26 |
| User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) BACK DISC REPAIR 2) BACK PAIN' (Site from System). | System | 15 Oct 2020 00:43:13 |
| Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) BACK DISC REPAIR 2) BACK PAIN' answered with '.' (Site from System). | Kim Calloway (b) (4) | 15 Oct 2020 00:43:13 |
| User entered 'DISC REPAIR OF BACK' reason for change: Data Entry Error | Kim Calloway (b) (4) | 15 Oct 2020 00:43:04 |
| User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) BACK DISC REPAIR 2) BACK PAIN' (Site from System). | Coder Import (b) (4) | 09 Oct 2020 23:26:23 |
| Data point term sent to Coder | System | 08 Oct 2020 22:22:20 |
| 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 '.' (Site from DM). | April Green (b) (4) | 08 Oct 2020 22:21:56 |
| Coding entries removed. | April Green (b) (4) | 08 Oct 2020 22:21:52 |

US3452332

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:36

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User entered 'DISC REPAIR TO BACK SECONDARY TO PAIN' reason for change: Data Entry Error | April Green (b) (4) | 08 Oct 2020 22:21:52 |
| 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) | 05 Oct 2020 04:41:32 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Intervertebral disc operation - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 12:44:14 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 12:44:14 |
| Data point term sent to Coder | System | 07 Aug 2020 21:42:58 |
| User entered 'BACK SURGERY TO REPAIR DISC' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:03 |

US3452332

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 2016' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:03 |

US3452332

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:03 |

US3452332

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | (b) (4) Kim Calloway (b) (4) | 07 Aug 2020 21:42:03 |

US3452332

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 2016' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:03 |

US3452332

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:03 |

US3452332

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 2016' | System | 07 Aug 2020 21:42:03 |

US3452332

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:36

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '2016' | System | 07 Aug 2020 21:42:03 |

US3452332

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 2016' | System | 07 Aug 2020 21:42:03 |

US3452332

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '2016' | System | 07 Aug 2020 21:42:03 |

US3452332

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:36

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| 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: Penicillin allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:43:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 21:43:53 |
| Data point term sent to Coder | System | 07 Aug 2020 21:42:58 |
| User entered 'ALLERGY TO PENICILLIN' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:22 |

US3452332

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 1995' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:22 |

US3452332

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:22 |

US3452332

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:22 |

US3452332

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 21:42:22 |

US3452332

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:22 |

US3452332

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 1995' | System | 07 Aug 2020 21:42:22 |

US3452332

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '1995' | System | 07 Aug 2020 21:42:22 |

US3452332

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:42:22 |

US3452332

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 07 Aug 2020 21:42:22 |

US3452332

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:36

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Oct 2020 00:46:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Oct 2020 00:46:25 |
| Data point term sent to Coder | System | 15 Oct 2020 00:45:27 |
| User entered 'BACK PAIN' | Kim Calloway (b) (4) | 15 Oct 2020 00:44:44 |

US3452332

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'UN UNK 2015' reason for change: | (b) (4) | |
| Data Entry Error | Kim Calloway (b) (4) | 19 Oct 2020 16:50:59 |
| User entered 'UN UNK 2016' | (b) (4) | |
| | Kim Calloway (b) (4) | 15 Oct 2020 00:44:44 |
| | (b) (4) | |

US3452332

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 15 Oct 2020 00:44:44 |

US3452332

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:36

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Kim Calloway (b) (4) | 19 Oct 2020 16:50:59 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 15 Oct 2020 00:44:44 |

US3452332

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:36

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty; reason for change Data Entry Error | Kim Calloway (b) (4) | 19 Oct 2020 16:50:59 |
| User entered 'UN UNK 2016' | Kim Calloway (b) (4) | 15 Oct 2020 00:44:44 |

US3452332

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:36

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 15 Oct 2020 00:44:44 |

US3452332

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'Jan 2015' | System | 19 Oct 2020 16:50:59 |
| User entered 'Jan 2016' | System | 15 Oct 2020 00:44:44 |

US3452332

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '2015' | System | 19 Oct 2020 16:50:59 |
| User entered '2016' | System | 15 Oct 2020 00:44:44 |

US3452332

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 19 Oct 2020 16:50:59 |
| User entered 'Jan 2016' | System | 15 Oct 2020 00:44:44 |

US3452332

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered empty. | System | 19 Oct 2020 16:50:59 |
| User entered '2016' | System | 15 Oct 2020 00:44:44 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 19 Aug 2020 18:23:09 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '07 Aug 2020' | Kim Calloway (b) (4) | 19 Aug 2020 18:23:09 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '15:06' | Kim Calloway (b) (4) | 19 Aug 2020 18:23:09 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered '07 Aug 2020 15:06' | System | 19 Aug 2020 18:23:09 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '69.2' in | (b) (4) | |
| | Kim Calloway (b) (4) | 19 Aug 2020 18:23:09 |
| | (b) (4) | |
| DataPoint set to visible. | System | 07 Aug 2020 19:28:33 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Weight \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '221.8' lb | (b) (4) Kim Calloway (b) (4) | 19 Aug 2020 18:23:09 |
| DataPoint set to visible. | (b) (4) System | 07 Aug 2020 19:28:33 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| Amendment Manager: User entered '32.63317' | System | 16 Sep 2020 23:48:03 |
| User entered '32.6' | System | 19 Aug 2020 18:23:09 |
| DataPoint set to visible. | System | 07 Aug 2020 19:28:33 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'kg/m2' | System | 19 Aug 2020 18:23:09 |
| DataPoint set to visible. | System | 07 Aug 2020 19:28:33 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Oct 2020 11:48:54 |
| Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '.' (Site from DM). | Kim Calloway (b) (4) (b) (4) | 30 Sep 2020 17:55:33 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kim Calloway (b) (4) (b) (4) | 30 Sep 2020 17:55:29 |
| User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 11:23:25 |
| User entered '98.8' F | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:23:09 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Kim Calloway (b) (4) | 30 Sep 2020 17:55:29 |
| User entered 'Oral (Oral)' | (b) (4) | |
| | Kim Calloway (b) (4) | 19 Aug 2020 18:23:09 |
| | (b) (4) | |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:23:09 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 30 Sep 2020 17:55:29 |
| User entered '61' | Kim Calloway (b) (4) | 19 Aug 2020 18:23:09 |
| | (b) (4) | |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'bpm' | System | 19 Aug 2020 18:23:09 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 30 Sep 2020 17:55:29 |
| User entered '16' | Kim Calloway (b) (4) | 19 Aug 2020 18:23:09 |
| | (b) (4) | |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'breaths/min' | System | 19 Aug 2020 18:23:09 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 30 Sep 2020 17:55:29 |
| User entered '140' | Kim Calloway (b) (4) | 19 Aug 2020 18:23:09 |
| | (b) (4) | |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'mmHg' | System | 19 Aug 2020 18:23:09 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 30 Sep 2020 17:55:29 |
| User entered '80' | Kim Calloway (b) (4) | 19 Aug 2020 18:23:09 |
| | (b) (4) | |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User entered 'mmHg' | System | 19 Aug 2020 18:23:09 |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| | | |

US3452332

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| | | |

US3452332

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 19:28:43 |

US3452332

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 06 Sep 2020 11:59:04 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 03 Sep 2020 15:56:30 |
| User entered '07 Aug 2020' | Kim Calloway (b) (4) (b) (4) | 07 Aug 2020 19:28:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

[Specify](#)

| Audit | User | Time (GMT) |
|-----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'TRUCK DRIVER' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'I' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '0' | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:36

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 19:57:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 21:42:43 |

US3452332

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 19:28:59 |

US3452332

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '07 Aug 2020' | (b) (4) Kim Calloway (b) (4) | 07 Aug 2020 19:28:59 |

US3452332

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Clinic (Clinic)' | Kim Calloway (b) (4) | 07 Aug 2020 19:28:59 |

US3452332

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'VISIT1' | System | 07 Aug 2020 19:28:59 |

US3452332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '07 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 19:24:29 |

US3452332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) | 21 Aug 2020 02:58:40 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 02:58:40 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 07 Aug 2020 19:24:29 |
| User entered '185244' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 19:24:29 |

US3452332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|-------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '>=65 years (3)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 19:24:29 |

US3452332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:43:01 |

US3452332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:43:01 |

US3452332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | (b) (4) Kim Calloway (b) (4) | 07 Aug 2020 21:43:01 |

US3452332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:36

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 21:43:01 |

US3452332

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:36

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 07 Aug 2020 21:43:01 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

Height

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Oct 2020 11:49:07 |
| Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '.' (Site from DM). | Kim Calloway (b) (4) (b) (4) | 30 Sep 2020 17:56:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kim Calloway (b) (4) (b) (4) | 30 Sep 2020 17:56:35 |
| User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 11:23:05 |
| User entered empty. | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:23:24 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

[Weight](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 30 Sep 2020 17:56:35 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

Height

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Oct 2020 11:49:07 |
| Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '.' (Site from DM). | Kim Calloway (b) (4) (b) (4) | 30 Sep 2020 17:56:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kim Calloway (b) (4) (b) (4) | 30 Sep 2020 17:56:35 |
| User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 11:23:05 |
| User entered empty. | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:23:24 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

[Weight](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 30 Sep 2020 17:56:35 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:23:24 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | Kim Calloway (b) (4) | 30 Sep 2020 17:56:35 |
| User entered 'No (N)' | (b) (4) | |
| | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) | 30 Sep 2020 17:56:35 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '15:06' reason for change: Data Entry Error | (b) (4) | |
| | Kim Calloway (b) (4) | 30 Sep 2020 17:56:35 |
| User entered empty. | (b) (4) | |
| | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '07 Aug 2020 15:06' | System | 30 Sep 2020 17:56:35 |
| User entered empty. | System | 19 Aug 2020 18:23:24 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '98.8' F reason for change: Data Entry Error | (b) (4) | |
| | Kim Calloway (b) (4) | 30 Sep 2020 17:56:35 |
| User entered empty. | (b) (4) | |
| | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4) | 30 Sep 2020 17:56:35 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '61' reason for change: Data Entry Error | (b) (4) | |
| | Kim Calloway (b) (4) | 30 Sep 2020 17:56:35 |
| User entered empty. | (b) (4) | |
| | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'bpm' | System | 30 Sep 2020 17:56:35 |
| User entered empty. | System | 19 Aug 2020 18:23:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '16' reason for change: Data Entry Error | (b) (4) | |
| | Kim Calloway (b) (4) | 30 Sep 2020 17:56:35 |
| User entered empty. | (b) (4) | |
| | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'breaths/min' | System | 30 Sep 2020 17:56:35 |
| User entered empty. | System | 19 Aug 2020 18:23:24 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '140' reason for change: Data Entry Error | (b) (4) | |
| | Kim Calloway (b) (4) | 30 Sep 2020 17:56:35 |
| User entered empty. | (b) (4) | |
| | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'mmHg' | System | 30 Sep 2020 17:56:35 |
| User entered empty. | System | 19 Aug 2020 18:23:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '81' reason for change: Data Entry Error | (b) (4) | |
| | Kim Calloway (b) (4) | 30 Sep 2020 17:56:35 |
| User entered empty. | (b) (4) | |
| | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'mmHg' | System | 30 Sep 2020 17:56:35 |
| User entered empty. | System | 19 Aug 2020 18:23:24 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

Height

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Oct 2020 11:49:07 |
| Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '.' (Site from DM). | Kim Calloway (b) (4) (b) (4) | 30 Sep 2020 17:56:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kim Calloway (b) (4) (b) (4) | 30 Sep 2020 17:56:35 |
| User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 11:23:05 |
| User entered empty. | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:23:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

[Weight](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 30 Sep 2020 17:56:35 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:23:24 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:23:53 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) Kim Calloway (b) (4) | 19 Aug 2020 18:23:53 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | (b) (4) | 19 Aug 2020 18:25:27 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | System | 19 Aug 2020 18:25:27 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | Kim Calloway (b) (4) | 19 Aug 2020 18:25:27 |
| User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System). | (b) (4) | 19 Aug 2020 18:24:06 |
| User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System | 19 Aug 2020 18:24:06 |
| User entered '08 Aug 2020' reason for change: Data Entry Error | System | 19 Aug 2020 18:24:06 |
| User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System). | Kim Calloway (b) (4) | 19 Aug 2020 18:24:06 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | (b) (4) | 19 Aug 2020 18:23:53 |
| User entered '06 Aug 2020' | System | 19 Aug 2020 18:23:53 |
| | Kim Calloway (b) (4) | 19 Aug 2020 18:23:53 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version. | (b) (4) | 21 Aug 2020 02:58:36 |
| User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | | 19 Aug 2020 18:25:27 |
| User closed query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | | 19 Aug 2020 18:24:06 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered by data change (Site from System). | System | 19 Aug 2020 18:24:06 |
| User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | | 19 Aug 2020 18:23:53 |
| User entered '16:13' | Kim Calloway (b) (4) | 19 Aug 2020 18:23:53 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '07 Aug 2020 16:13' | System | 19 Aug 2020 18:25:27 |
| User entered '08 Aug 2020 16:13' | System | 19 Aug 2020 18:24:06 |
| User entered '06 Aug 2020 16:13' | System | 19 Aug 2020 18:23:53 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '98.3' F | Kim Calloway (b) (4) | 19 Aug 2020 18:23:53 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Oral (Oral)' | Kim Calloway (b) (4) | 19 Aug 2020 18:23:53 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) Kim Calloway (b) (4) | 19 Aug 2020 18:23:53 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '63' | Kim Calloway (b) (4) | 19 Aug 2020 18:23:53 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'bpm' | System | 19 Aug 2020 18:23:53 |

US3452332

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '14' | (b) (4) Kim Calloway (b) (4) | 19 Aug 2020 18:23:53 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'breaths/min' | System | 19 Aug 2020 18:23:53 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '131' | Kim Calloway (b) (4) | 19 Aug 2020 18:23:53 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'mmHg' | System | 19 Aug 2020 18:23:53 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '77' | (b) (4) Kim Calloway (b) (4) | 19 Aug 2020 18:23:53 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'mmHg' | System | 19 Aug 2020 18:23:53 |

US3452332

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| | Kim Calloway (b) (4) | 08 Oct 2020 20:37:58 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Kim Calloway (b) (4) | 07 Aug 2020 19:29:16 |
| | (b) (4) | |

US3452332

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Kim Calloway (b) (4) | 08 Oct 2020 20:37:58 |
| User entered '07 Aug 2020' | (b) (4) | |
| | Kim Calloway (b) (4) | 07 Aug 2020 19:29:16 |
| | (b) (4) | |

US3452332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 20:41:30 |

US3452332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 20:41:30 |

US3452332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 07 Aug 2020 20:41:30 |

US3452332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '07 Aug 2020' | Kim Calloway (b) (4) | 07 Aug 2020 20:41:30 |

US3452332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '15:38' | Kim Calloway (b) (4) | 07 Aug 2020 20:41:30 |

US3452332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '07 Aug 2020 15:38' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Right Arm (RIGHT ARM)' | Kim Calloway (b) (4) | 07 Aug 2020 20:41:30 |

US3452332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'ONCE' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'INTRAMUSCULAR' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 19 Aug 2020 18:24:35 |

US3452332

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '07 Aug 2020' | (b) (4) Kim Calloway (b) (4) | 19 Aug 2020 18:24:35 |

US3452332

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '15:25' | (b) (4) Kim Calloway (b) (4) | 19 Aug 2020 18:24:35 |

US3452332

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '07 Aug 2020 15:25' | System | 19 Aug 2020 18:24:35 |

US3452332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:49:36

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '07 Aug 2020' | Kim Calloway (b) (4) | 19 Aug 2020 18:24:54 |

US3452332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:36

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:24:54 |

US3452332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:36

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 19 Aug 2020 18:24:54 |

US3452332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:36

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '15:29' | Kim Calloway (b) (4) | 19 Aug 2020 18:24:54 |

US3452332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '07 Aug 2020 15:29' | System | 19 Aug 2020 18:24:54 |

US3452332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:36

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:25:16 |

US3452332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:36

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 19 Aug 2020 18:25:16 |

US3452332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:36

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '15:29' | Kim Calloway (b) (4) | 19 Aug 2020 18:25:16 |

US3452332

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '07 Aug 2020 15:29' | System | 19 Aug 2020 18:25:16 |

US3452332

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 07 Aug 2020 19:29:24 |

US3452332

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '1' | System | 07 Aug 2020 19:29:24 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:10:55', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '13ee8aa2-9a52-4d44-a6a0-17f5cb3623c4' | System | 07 Aug 2020 21:11:23 |
| User entered 'Yes (Y)' | System | 07 Aug 2020 21:11:23 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:11:07', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '13ee8aa2-9a52-4d44-a6a0-17f5cb3623c4' User entered '98.3' | System | 07 Aug 2020 21:11:23 |
| | System | 07 Aug 2020 21:11:23 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:11:14', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '13ee8aa2-9a52-4d44-a6a0-17f5cb3623c4' | System | 07 Aug 2020 21:11:23 |
| User entered 'No (N)' | System | 07 Aug 2020 21:11:23 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:11:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '13ee8aa2-9a52-4d44-a6a0-17f5cb3623c4' User entered '07 Aug 2020 16:11' | System | 07 Aug 2020 21:11:23 |
| | System | 07 Aug 2020 21:11:23 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Aug 2020 15:58' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Aug 2020 18:28' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:26:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6d1c7b2f-c80d-4a5b-9269-f6d3d05cab3e' User entered 'Yes (Y)' | System | 08 Aug 2020 00:28:00 |
| | System | 08 Aug 2020 00:28:00 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:27:02', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6d1c7b2f-c80d-4a5b-9269-f6d3d05cab3e' User entered '96.5' | System | 08 Aug 2020 00:28:00 |
| | System | 08 Aug 2020 00:28:00 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:27:11', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6d1c7b2f-c80d-4a5b-9269-f6d3d05cab3e' User entered 'No (N)' | System | 08 Aug 2020 00:28:00 |
| | System | 08 Aug 2020 00:28:00 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:27:36', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6d1c7b2f-c80d-4a5b-9269-f6d3d05cab3e' User entered '07 Aug 2020 19:27' | System | 08 Aug 2020 00:28:00 |
| | System | 08 Aug 2020 00:28:00 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Aug 2020 19:23' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 2' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:02:55', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'dd80ab2f-1f1d-434e-8080-9943a04b9c6c' User entered 'Yes (Y)' | System | 08 Aug 2020 17:03:33 |
| | System | 08 Aug 2020 17:03:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:03:02', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'dd80ab2f-1f1d-434e-8080-9943a04b9c6c' User entered '97.8' | System | 08 Aug 2020 17:03:33 |
| | System | 08 Aug 2020 17:03:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:03:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'dd80ab2f-1f1d-434e-8080-9943a04b9c6c' | System | 08 Aug 2020 17:03:33 |
| User entered 'No (N)' | System | 08 Aug 2020 17:03:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:03:31', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'dd80ab2f-1f1d-434e-8080-9943a04b9c6c' User entered '08 Aug 2020 12:03' | System | 08 Aug 2020 17:03:33 |
| | System | 08 Aug 2020 17:03:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 3' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:03:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '3d616ec0-082f-4198-ba23-0fc510fa7243' | System | 09 Aug 2020 17:04:17 |
| User entered 'Yes (Y)' | System | 09 Aug 2020 17:04:17 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:03:26', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '3d616ec0-082f-4198-ba23-0fc510fa7243' User entered '97.8' | System | 09 Aug 2020 17:04:17 |
| | System | 09 Aug 2020 17:04:17 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:03:37', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '3d616ec0-082f-4198-ba23-0fc510fa7243' | System | 09 Aug 2020 17:04:17 |
| User entered 'No (N)' | System | 09 Aug 2020 17:04:17 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:04:10', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '3d616ec0-082f-4198-ba23-0fc510fa7243' | System | 09 Aug 2020 17:04:17 |
| User entered '09 Aug 2020 12:04' | System | 09 Aug 2020 17:04:17 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 4' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:03:39', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '681ff32f-499e-4c1b-a00a-71cb5dbf3c59' User entered 'Yes (Y)' | System | 10 Aug 2020 17:04:11 |
| | System | 10 Aug 2020 17:04:11 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:03:46', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '681ff32f-499e-4c1b-a00a-71cb5dbf3c59' User entered '97.1' | System | 10 Aug 2020 17:04:11 |
| | System | 10 Aug 2020 17:04:11 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:03:51', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '681ff32f-499e-4c1b-a00a-71cb5dbf3c59' | System | 10 Aug 2020 17:04:11 |
| User entered 'No (N)' | System | 10 Aug 2020 17:04:11 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:04:08', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '681ff32f-499e-4c1b-a00a-71cb5dbf3c59' | System | 10 Aug 2020 17:04:11 |
| User entered '10 Aug 2020 12:04' | System | 10 Aug 2020 17:04:11 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 5' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:24:03', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e42806e3-9c81-40d5-95c0-216038a31d6d' User entered 'Yes (Y)' | System | 11 Aug 2020 17:24:33 |
| | System | 11 Aug 2020 17:24:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:24:10', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e42806e3-9c81-40d5-95c0-216038a31d6d' User entered '97.6' | System | 11 Aug 2020 17:24:33 |
| | System | 11 Aug 2020 17:24:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:24:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e42806e3-9c81-40d5-95c0-216038a31d6d' | System | 11 Aug 2020 17:24:33 |
| User entered 'No (N)' | System | 11 Aug 2020 17:24:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:24:32', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e42806e3-9c81-40d5-95c0-216038a31d6d' User entered '11 Aug 2020 12:24' | System | 11 Aug 2020 17:24:33 |
| | System | 11 Aug 2020 17:24:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 6' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:03:10', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2af6fa06-4c9d-4e2f-8804-63e64744219b' | System | 12 Aug 2020 17:03:38 |
| User entered 'Yes (Y)' | System | 12 Aug 2020 17:03:38 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:03:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2af6fa06-4c9d-4e2f-8804-63e64744219b' User entered '97.1' | System | 12 Aug 2020 17:03:38 |
| | System | 12 Aug 2020 17:03:38 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:03:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2af6fa06-4c9d-4e2f-8804-63e64744219b' | System | 12 Aug 2020 17:03:38 |
| User entered 'No (N)' | System | 12 Aug 2020 17:03:38 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:03:31', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2af6fa06-4c9d-4e2f-8804-63e64744219b' | System | 12 Aug 2020 17:03:38 |
| User entered '12 Aug 2020 12:03' | System | 12 Aug 2020 17:03:38 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 7' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:51:02', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '63f461fb-7e62-47c8-89ef-e6beb6434ead' User entered 'Yes (Y)' | System | 13 Aug 2020 17:51:27 |
| | System | 13 Aug 2020 17:51:27 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:51:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '63f461fb-7e62-47c8-89ef-e6beb6434ead' User entered '96.5' | System | 13 Aug 2020 17:51:27 |
| | System | 13 Aug 2020 17:51:27 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:51:18', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '63f461fb-7e62-47c8-89ef-e6beb6434ead' | System | 13 Aug 2020 17:51:27 |
| User entered 'No (N)' | System | 13 Aug 2020 17:51:27 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:51:26', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '63f461fb-7e62-47c8-89ef-e6beb6434ead' User entered '13 Aug 2020 12:51' | System | 13 Aug 2020 17:51:27 |
| | System | 13 Aug 2020 17:51:27 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:11:29', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '25adb5e9-da75-45a0-b37a-ce2f1fb45e1f' User entered 'None (1)' | System | 07 Aug 2020 21:12:04 |
| | System | 07 Aug 2020 21:12:04 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:11:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '25adb5e9-da75-45a0-b37a-ce2f1fb45e1f' User entered 'No (N)' | System | 07 Aug 2020 21:12:04 |
| | System | 07 Aug 2020 21:12:04 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:11:39', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '25adb5e9-da75-45a0-b37a-ce2f1fb45e1f' User entered 'No (N)' | System | 07 Aug 2020 21:12:04 |
| | System | 07 Aug 2020 21:12:04 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:11:47', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '25adb5e9-da75-45a0-b37a-ce2f1fb45e1f' User entered 'None (1)' | System | 07 Aug 2020 21:12:04 |
| | System | 07 Aug 2020 21:12:04 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:11:57', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '25adb5e9-da75-45a0-b37a-ce2f1fb45e1f' User entered '07 Aug 2020 16:11' | System | 07 Aug 2020 21:12:04 |
| | System | 07 Aug 2020 21:12:04 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Aug 2020 15:58' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Aug 2020 18:28' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:28:08', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '14669e01-32b1-4c57-810a-b837fdf85a99' | System | 08 Aug 2020 00:28:45 |
| User entered 'None (1)' | System | 08 Aug 2020 00:28:45 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:28:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '14669e01-32b1-4c57-810a-b837fdf85a99' | System | 08 Aug 2020 00:28:45 |
| User entered 'No (N)' | System | 08 Aug 2020 00:28:45 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:28:22', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '14669e01-32b1-4c57-810a-b837fdf85a99' | System | 08 Aug 2020 00:28:45 |
| User entered 'No (N)' | System | 08 Aug 2020 00:28:45 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:28:32', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '14669e01-32b1-4c57-810a-b837fdf85a99' | System | 08 Aug 2020 00:28:45 |
| User entered 'None (1)' | System | 08 Aug 2020 00:28:45 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:28:41', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '14669e01-32b1-4c57-810a-b837fdf85a99' | System | 08 Aug 2020 00:28:45 |
| User entered '07 Aug 2020 19:28' | System | 08 Aug 2020 00:28:45 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Aug 2020 19:23' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 2' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:03:39', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f5421748-53c3-4cbc-8775-d9318450a783' | System | 08 Aug 2020 17:04:33 |
| User entered 'None (1)' | System | 08 Aug 2020 17:04:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:03:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f5421748-53c3-4cbc-8775-d9318450a783' User entered 'No (N)' | System | 08 Aug 2020 17:04:33 |
| | System | 08 Aug 2020 17:04:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:04:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f5421748-53c3-4cbc-8775-d9318450a783' User entered 'No (N)' | System | 08 Aug 2020 17:04:33 |
| | System | 08 Aug 2020 17:04:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:04:09', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f5421748-53c3-4cbc-8775-d9318450a783' | System | 08 Aug 2020 17:04:33 |
| User entered 'None (1)' | System | 08 Aug 2020 17:04:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:04:30', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f5421748-53c3-4cbc-8775-d9318450a783' User entered '08 Aug 2020 12:04' | System | 08 Aug 2020 17:04:33 |
| | System | 08 Aug 2020 17:04:33 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 3' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:04:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '05b8c1ed-a6a9-4bc8-a77c-3674f03f8341' User entered 'None (1)' | System | 09 Aug 2020 17:05:24 |
| | System | 09 Aug 2020 17:05:24 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:04:32', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '05b8c1ed-a6a9-4bc8-a77c-3674f03f8341' User entered 'No (N)' | System | 09 Aug 2020 17:05:24 |
| | System | 09 Aug 2020 17:05:24 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:04:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '05b8c1ed-a6a9-4bc8-a77c-3674f03f8341' User entered 'No (N)' | System | 09 Aug 2020 17:05:24 |
| | System | 09 Aug 2020 17:05:24 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:05:05', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '05b8c1ed-a6a9-4bc8-a77c-3674f03f8341' User entered 'None (1)' | System | 09 Aug 2020 17:05:24 |
| | System | 09 Aug 2020 17:05:24 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:05:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '05b8c1ed-a6a9-4bc8-a77c-3674f03f8341' User entered '09 Aug 2020 12:05' | System | 09 Aug 2020 17:05:24 |
| | System | 09 Aug 2020 17:05:24 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 4' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:04:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '025081ac-d80d-4e07-9a49-162591336c43' User entered 'None (1)' | System | 10 Aug 2020 17:05:01 |
| | System | 10 Aug 2020 17:05:01 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:04:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '025081ac-d80d-4e07-9a49-162591336c43' | System | 10 Aug 2020 17:05:01 |
| User entered 'No (N)' | System | 10 Aug 2020 17:05:01 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:04:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '025081ac-d80d-4e07-9a49-162591336c43' User entered 'No (N)' | System | 10 Aug 2020 17:05:01 |
| | System | 10 Aug 2020 17:05:01 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:04:41', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '025081ac-d80d-4e07-9a49-162591336c43' | System | 10 Aug 2020 17:05:01 |
| User entered 'None (1)' | System | 10 Aug 2020 17:05:01 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:04:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '025081ac-d80d-4e07-9a49-162591336c43' User entered '10 Aug 2020 12:04' | System | 10 Aug 2020 17:05:01 |
| | System | 10 Aug 2020 17:05:01 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 5' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:24:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2dc24c69-e019-4857-ae1a-50c87ce25db5' User entered 'None (1)' | System | 11 Aug 2020 17:25:04 |
| | System | 11 Aug 2020 17:25:04 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:24:46', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2dc24c69-e019-4857-ae1a-50c87ce25db5' User entered 'No (N)' | System | 11 Aug 2020 17:25:04 |
| | System | 11 Aug 2020 17:25:04 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:24:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2dc24c69-e019-4857-ae1a-50c87ce25db5' User entered 'No (N)' | System | 11 Aug 2020 17:25:04 |
| | System | 11 Aug 2020 17:25:04 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:24:54', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2dc24c69-e019-4857-ae1a-50c87ce25db5' User entered 'None (1)' | System | 11 Aug 2020 17:25:04 |
| | System | 11 Aug 2020 17:25:04 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:24:59', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2dc24c69-e019-4857-ae1a-50c87ce25db5' User entered '11 Aug 2020 12:24' | System | 11 Aug 2020 17:25:04 |
| | System | 11 Aug 2020 17:25:04 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 6' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:03:39', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9718c695-ea80-449e-bc6c-8d73a1a493bb' User entered 'None (1)' | System | 12 Aug 2020 17:03:58 |
| | System | 12 Aug 2020 17:03:58 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:03:43', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9718c695-ea80-449e-bc6c-8d73a1a493bb' User entered 'No (N)' | System | 12 Aug 2020 17:03:58 |
| | System | 12 Aug 2020 17:03:58 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:03:47', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9718c695-ea80-449e-bc6c-8d73a1a493bb' User entered 'No (N)' | System | 12 Aug 2020 17:03:58 |
| | System | 12 Aug 2020 17:03:58 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:03:52', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9718c695-ea80-449e-bc6c-8d73a1a493bb' | System | 12 Aug 2020 17:03:58 |
| User entered 'None (1)' | System | 12 Aug 2020 17:03:58 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:03:56', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9718c695-ea80-449e-bc6c-8d73a1a493bb' User entered '12 Aug 2020 12:03' | System | 12 Aug 2020 17:03:58 |
| | System | 12 Aug 2020 17:03:58 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 7' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:51:34', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f975ff66-04fe-47dd-8e2f-b23861be0820' | System | 13 Aug 2020 17:51:56 |
| User entered 'None (1)' | System | 13 Aug 2020 17:51:56 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:51:38', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f975ff66-04fe-47dd-8e2f-b23861be0820' | System | 13 Aug 2020 17:51:56 |
| User entered 'No (N)' | System | 13 Aug 2020 17:51:56 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:51:41', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f975ff66-04fe-47dd-8e2f-b23861be0820' | System | 13 Aug 2020 17:51:56 |
| User entered 'No (N)' | System | 13 Aug 2020 17:51:56 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:51:46', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f975ff66-04fe-47dd-8e2f-b23861be0820' | System | 13 Aug 2020 17:51:56 |
| User entered 'None (1)' | System | 13 Aug 2020 17:51:56 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:51:54', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f975ff66-04fe-47dd-8e2f-b23861be0820' | System | 13 Aug 2020 17:51:56 |
| User entered '13 Aug 2020 12:51' | System | 13 Aug 2020 17:51:56 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:12:09', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48bb4a62-4911-4f2f-9bcc-893e302492ae' User entered 'None (0)' | System | 07 Aug 2020 21:12:42 |
| | System | 07 Aug 2020 21:12:42 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:12:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48bb4a62-4911-4f2f-9bcc-893e302492ae' User entered 'None (0)' | System | 07 Aug 2020 21:12:42 |
| | System | 07 Aug 2020 21:12:42 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:12:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48bb4a62-4911-4f2f-9bcc-893e302492ae' User entered 'None (0)' | System | 07 Aug 2020 21:12:42 |
| | System | 07 Aug 2020 21:12:42 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:12:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48bb4a62-4911-4f2f-9bcc-893e302492ae' User entered 'None (0)' | System | 07 Aug 2020 21:12:42 |
| | System | 07 Aug 2020 21:12:42 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:12:24', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48bb4a62-4911-4f2f-9bcc-893e302492ae' User entered 'None (0)' | System | 07 Aug 2020 21:12:42 |
| | System | 07 Aug 2020 21:12:42 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:12:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48bb4a62-4911-4f2f-9bcc-893e302492ae' User entered 'None (0)' | System | 07 Aug 2020 21:12:42 |
| | System | 07 Aug 2020 21:12:42 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:12:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48bb4a62-4911-4f2f-9bcc-893e302492ae' User entered 'No (N)' | System | 07 Aug 2020 21:12:42 |
| | System | 07 Aug 2020 21:12:42 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T16:12:38', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48bb4a62-4911-4f2f-9bcc-893e302492ae' User entered '07 Aug 2020 16:12' | System | 07 Aug 2020 21:12:42 |
| | System | 07 Aug 2020 21:12:42 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Aug 2020 15:58' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Aug 2020 18:28' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:29:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '84d59f92-07c1-4e72-b869-6cef30241256' User entered 'None (0)' | System | 08 Aug 2020 00:32:54 |
| | System | 08 Aug 2020 00:32:54 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:29:29', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '84d59f92-07c1-4e72-b869-6cef30241256' User entered 'None (0)' | System | 08 Aug 2020 00:32:54 |
| | System | 08 Aug 2020 00:32:54 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:29:43', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '84d59f92-07c1-4e72-b869-6cef30241256' User entered 'None (0)' | System | 08 Aug 2020 00:32:54 |
| | System | 08 Aug 2020 00:32:54 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:29:50', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '84d59f92-07c1-4e72-b869-6cef30241256' User entered 'None (0)' | System | 08 Aug 2020 00:32:54 |
| | System | 08 Aug 2020 00:32:54 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:29:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '84d59f92-07c1-4e72-b869-6cef30241256' User entered 'None (0)' | System | 08 Aug 2020 00:32:54 |
| | System | 08 Aug 2020 00:32:54 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:30:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '84d59f92-07c1-4e72-b869-6cef30241256' User entered 'None (0)' | System | 08 Aug 2020 00:32:54 |
| | System | 08 Aug 2020 00:32:54 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:30:15', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '84d59f92-07c1-4e72-b869-6cef30241256' User entered 'No (N)' | System | 08 Aug 2020 00:32:54 |
| | System | 08 Aug 2020 00:32:54 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-07T19:30:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '84d59f92-07c1-4e72-b869-6cef30241256' User entered '07 Aug 2020 19:30' | System | 08 Aug 2020 00:32:54 |
| | System | 08 Aug 2020 00:32:54 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Aug 2020 19:23' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 2' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:04:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a268cb74-7d5e-4cf9-8895-9762c8094075' User entered 'None (0)' | System | 08 Aug 2020 17:07:18 |
| | System | 08 Aug 2020 17:07:18 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:05:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a268cb74-7d5e-4cf9-8895-9762c8094075' User entered 'None (0)' | System | 08 Aug 2020 17:07:18 |
| | System | 08 Aug 2020 17:07:18 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:06:29', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a268cb74-7d5e-4cf9-8895-9762c8094075' | System | 08 Aug 2020 17:07:18 |
| User entered 'No interference with activity (1)' | System | 08 Aug 2020 17:07:18 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:06:41', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a268cb74-7d5e-4cf9-8895-9762c8094075' User entered 'None (0)' | System | 08 Aug 2020 17:07:18 |
| | System | 08 Aug 2020 17:07:18 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:06:45', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a268cb74-7d5e-4cf9-8895-9762c8094075' User entered 'None (0)' | System | 08 Aug 2020 17:07:18 |
| | System | 08 Aug 2020 17:07:18 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:06:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a268cb74-7d5e-4cf9-8895-9762c8094075' User entered 'None (0)' | System | 08 Aug 2020 17:07:18 |
| | System | 08 Aug 2020 17:07:18 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:06:54', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a268cb74-7d5e-4cf9-8895-9762c8094075' | System | 08 Aug 2020 17:07:18 |
| User entered 'No (N)' | System | 08 Aug 2020 17:07:18 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-08T12:07:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a268cb74-7d5e-4cf9-8895-9762c8094075' User entered '08 Aug 2020 12:07' | System | 08 Aug 2020 17:07:18 |
| | System | 08 Aug 2020 17:07:18 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 3' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:05:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7786af51-9ec3-49d8-8688-5861214b57c2' | System | 09 Aug 2020 17:07:02 |
| User entered 'None (0)' | System | 09 Aug 2020 17:07:02 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:05:59', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7786af51-9ec3-49d8-8688-5861214b57c2' | System | 09 Aug 2020 17:07:02 |
| User entered 'None (0)' | System | 09 Aug 2020 17:07:02 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:06:06', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7786af51-9ec3-49d8-8688-5861214b57c2' | System | 09 Aug 2020 17:07:02 |
| User entered 'None (0)' | System | 09 Aug 2020 17:07:02 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:06:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7786af51-9ec3-49d8-8688-5861214b57c2' | System | 09 Aug 2020 17:07:02 |
| User entered 'None (0)' | System | 09 Aug 2020 17:07:02 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:06:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7786af51-9ec3-49d8-8688-5861214b57c2' | System | 09 Aug 2020 17:07:02 |
| User entered 'None (0)' | System | 09 Aug 2020 17:07:02 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:06:26', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7786af51-9ec3-49d8-8688-5861214b57c2' | System | 09 Aug 2020 17:07:02 |
| User entered 'None (0)' | System | 09 Aug 2020 17:07:02 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:06:35', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7786af51-9ec3-49d8-8688-5861214b57c2' | System | 09 Aug 2020 17:07:02 |
| User entered 'No (N)' | System | 09 Aug 2020 17:07:02 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-09T12:06:59', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7786af51-9ec3-49d8-8688-5861214b57c2' | System | 09 Aug 2020 17:07:02 |
| User entered '09 Aug 2020 12:06' | System | 09 Aug 2020 17:07:02 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 4' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:05:03', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48a69cff-5be8-4349-8fd4-55cc14272e50' User entered 'None (0)' | System | 10 Aug 2020 17:05:59 |
| | System | 10 Aug 2020 17:05:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:05:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48a69cff-5be8-4349-8fd4-55cc14272e50' User entered 'None (0)' | System | 10 Aug 2020 17:05:59 |
| | System | 10 Aug 2020 17:05:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:05:18', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48a69cff-5be8-4349-8fd4-55cc14272e50' User entered 'None (0)' | System | 10 Aug 2020 17:05:59 |
| | System | 10 Aug 2020 17:05:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:05:25', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48a69cff-5be8-4349-8fd4-55cc14272e50' User entered 'None (0)' | System | 10 Aug 2020 17:05:59 |
| | System | 10 Aug 2020 17:05:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:05:29', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48a69cff-5be8-4349-8fd4-55cc14272e50' User entered 'None (0)' | System | 10 Aug 2020 17:05:59 |
| | System | 10 Aug 2020 17:05:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:05:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48a69cff-5be8-4349-8fd4-55cc14272e50' User entered 'None (0)' | System | 10 Aug 2020 17:05:59 |
| | System | 10 Aug 2020 17:05:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:05:43', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48a69cff-5be8-4349-8fd4-55cc14272e50' | System | 10 Aug 2020 17:05:59 |
| User entered 'No (N)' | System | 10 Aug 2020 17:05:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-10T12:05:57', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '48a69cff-5be8-4349-8fd4-55cc14272e50' | System | 10 Aug 2020 17:05:59 |
| User entered '10 Aug 2020 12:05' | System | 10 Aug 2020 17:05:59 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 5' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:25:05', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '827e2353-7f21-4eed-ac4b-18a835f1a3e5' User entered 'None (0)' | System | 11 Aug 2020 17:25:49 |
| | System | 11 Aug 2020 17:25:49 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:25:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '827e2353-7f21-4eed-ac4b-18a835f1a3e5' User entered 'None (0)' | System | 11 Aug 2020 17:25:49 |
| | System | 11 Aug 2020 17:25:49 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:25:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '827e2353-7f21-4eed-ac4b-18a835f1a3e5' User entered 'None (0)' | System | 11 Aug 2020 17:25:49 |
| | System | 11 Aug 2020 17:25:49 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:25:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '827e2353-7f21-4eed-ac4b-18a835f1a3e5' User entered 'None (0)' | System | 11 Aug 2020 17:25:49 |
| | System | 11 Aug 2020 17:25:49 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:25:24', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '827e2353-7f21-4eed-ac4b-18a835f1a3e5' User entered 'None (0)' | System | 11 Aug 2020 17:25:49 |
| | System | 11 Aug 2020 17:25:49 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:25:28', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '827e2353-7f21-4eed-ac4b-18a835f1a3e5' User entered 'None (0)' | System | 11 Aug 2020 17:25:49 |
| | System | 11 Aug 2020 17:25:49 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:25:35', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '827e2353-7f21-4eed-ac4b-18a835f1a3e5' | System | 11 Aug 2020 17:25:49 |
| User entered 'No (N)' | System | 11 Aug 2020 17:25:49 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-11T12:25:45', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '827e2353-7f21-4eed-ac4b-18a835f1a3e5' | System | 11 Aug 2020 17:25:49 |
| User entered '11 Aug 2020 12:25' | System | 11 Aug 2020 17:25:49 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 6' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:04:06', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'debae6a2-7c12-4659-8c48-de7f18b91bd4' User entered 'None (0)' | System | 12 Aug 2020 17:04:44 |
| | System | 12 Aug 2020 17:04:44 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:04:11', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'debae6a2-7c12-4659-8c48-de7f18b91bd4' User entered 'None (0)' | System | 12 Aug 2020 17:04:44 |
| | System | 12 Aug 2020 17:04:44 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:04:15', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'debae6a2-7c12-4659-8c48-de7f18b91bd4' User entered 'None (0)' | System | 12 Aug 2020 17:04:44 |
| | System | 12 Aug 2020 17:04:44 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:04:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'debae6a2-7c12-4659-8c48-de7f18b91bd4' User entered 'None (0)' | System | 12 Aug 2020 17:04:44 |
| | System | 12 Aug 2020 17:04:44 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:04:25', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'debae6a2-7c12-4659-8c48-de7f18b91bd4' User entered 'None (0)' | System | 12 Aug 2020 17:04:44 |
| | System | 12 Aug 2020 17:04:44 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:04:30', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'debae6a2-7c12-4659-8c48-de7f18b91bd4' User entered 'None (0)' | System | 12 Aug 2020 17:04:44 |
| | System | 12 Aug 2020 17:04:44 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:04:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'debae6a2-7c12-4659-8c48-de7f18b91bd4' User entered 'No (N)' | System | 12 Aug 2020 17:04:44 |
| | System | 12 Aug 2020 17:04:44 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-12T12:04:40', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'debae6a2-7c12-4659-8c48-de7f18b91bd4' User entered '12 Aug 2020 12:04' | System | 12 Aug 2020 17:04:44 |
| | System | 12 Aug 2020 17:04:44 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 7' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:51:59', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b8878d32-b43f-4a23-ba26-587db1b457d4' User entered 'None (0)' | System | 13 Aug 2020 17:52:32 |
| | System | 13 Aug 2020 17:52:32 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:52:04', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b8878d32-b43f-4a23-ba26-587db1b457d4' User entered 'None (0)' | System | 13 Aug 2020 17:52:32 |
| | System | 13 Aug 2020 17:52:32 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:52:08', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b8878d32-b43f-4a23-ba26-587db1b457d4' User entered 'None (0)' | System | 13 Aug 2020 17:52:32 |
| | System | 13 Aug 2020 17:52:32 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:52:10', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b8878d32-b43f-4a23-ba26-587db1b457d4' User entered 'None (0)' | System | 13 Aug 2020 17:52:32 |
| | System | 13 Aug 2020 17:52:32 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:52:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b8878d32-b43f-4a23-ba26-587db1b457d4' User entered 'None (0)' | System | 13 Aug 2020 17:52:32 |
| | System | 13 Aug 2020 17:52:32 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:52:15', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b8878d32-b43f-4a23-ba26-587db1b457d4' User entered 'None (0)' | System | 13 Aug 2020 17:52:32 |
| | System | 13 Aug 2020 17:52:32 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:52:25', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b8878d32-b43f-4a23-ba26-587db1b457d4' | System | 13 Aug 2020 17:52:32 |
| User entered 'No (N)' | System | 13 Aug 2020 17:52:32 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-08-13T12:52:29', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b8878d32-b43f-4a23-ba26-587db1b457d4' | System | 13 Aug 2020 17:52:32 |
| User entered '13 Aug 2020 12:52' | System | 13 Aug 2020 17:52:32 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) April Green (b) (4) (b) (4) | 18 Aug 2020 19:49:42 |

US3452332

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '14 Aug 2020' | (b) (4) April Green (b) (4) (b) (4) | 18 Aug 2020 19:49:42 |

US3452332

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) April Green (b) (4) (b) (4) | 18 Aug 2020 19:49:42 |

US3452332

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) April Green (b) (4) (b) (4) | 18 Aug 2020 19:49:42 |

US3452332

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) April Green (b) (4) (b) (4) | 28 Aug 2020 19:55:05 |

US3452332

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '1' | System | 28 Aug 2020 19:55:05 |

US3452332

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | (b) (4) April Green (b) (4) (b) (4) | 28 Aug 2020 19:55:17 |

US3452332

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '21 Aug 2020' | (b) (4) April Green (b) (4) (b) (4) | 28 Aug 2020 19:55:17 |

US3452332

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) April Green (b) (4) (b) (4) | 28 Aug 2020 19:55:17 |

US3452332

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | (b) (4) April Green (b) (4) (b) (4) | 28 Aug 2020 19:55:17 |

US3452332

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | (b) (4) April Green (b) (4) (b) (4) | 28 Aug 2020 19:55:21 |

US3452332

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'I' | System | 28 Aug 2020 19:55:21 |

US3452332

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) April Green (b) (4) (b) (4) | 28 Aug 2020 19:55:32 |

US3452332

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '28 Aug 2020' | (b) (4) April Green (b) (4) (b) (4) | 28 Aug 2020 19:55:32 |

US3452332

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) April Green (b) (4) (b) (4) | 28 Aug 2020 19:55:32 |

US3452332

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) April Green (b) (4) (b) (4) | 28 Aug 2020 19:55:32 |

US3452332

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Sep 2020 15:56:19 |

US3452332

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'I' | System | 03 Sep 2020 15:56:19 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Sep 2020 15:56:30 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System). | (b) (4) (b) (4), (b) (6) | 04 Sep 2020 02:00:03 |
| Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'DATE IS CORRECT' (Site from System). | Kim Calloway (b) (4) (b) (4) | 03 Sep 2020 15:56:34 |
| User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System). | System | 03 Sep 2020 15:56:30 |
| User entered '03 Sep 2020' | Kim Calloway (b) (4) (b) (4) | 03 Sep 2020 15:56:30 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Clinic (Clinic)' | Kim Calloway (b) (4) | 03 Sep 2020 15:56:30 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'VISIT2' | System | 03 Sep 2020 15:56:30 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Kim Calloway (b) (4) | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '03 Sep 2020' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '11:17' | Kim Calloway (b) (4) | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '03 Sep 2020 11:17' | System | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '97.7' F | Kim Calloway (b) (4) | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Oral (Oral)' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '63' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'bpm' | System | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '16' | Kim Calloway (b) (4) | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'breaths/min' | System | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '138' | Kim Calloway (b) (4) | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'mmHg' | System | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '85' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'mmHg' | System | 03 Sep 2020 16:57:25 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Kim Calloway (b) (4) (b) (4) | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '03 Sep 2020' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '12:24' reason for change: Data Entry Error | (b) (4) | |
| | Kim Calloway (b) (4) | 08 Oct 2020 20:38:23 |
| User entered '12:15' | (b) (4) | |
| | Kim Calloway (b) (4) | 03 Sep 2020 17:29:10 |
| | (b) (4) | |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '03 Sep 2020 12:24' | System | 08 Oct 2020 20:38:23 |
| User entered '03 Sep 2020 12:15' | System | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '98.3' F | Kim Calloway (b) (4) | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Oral (Oral)' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '69' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'bpm' | System | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '16' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'breaths/min' | System | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '134' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'mmHg' | System | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '80' | Kim Calloway (b) (4) | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'mmHg' | System | 03 Sep 2020 17:29:10 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Sep 2020 15:56:44 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '03 Sep 2020' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 15:56:44 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 16:57:52 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 03 Sep 2020 16:57:52 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 03 Sep 2020 16:57:52 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '03 Sep 2020' | Kim Calloway (b) (4) | 03 Sep 2020 16:57:52 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '11:45' | Kim Calloway (b) (4) | 03 Sep 2020 16:57:52 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '03 Sep 2020 11:45' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Right Arm (RIGHT ARM)' | Kim Calloway (b) (4) | 03 Sep 2020 16:57:52 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'ONCE' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'INTRAMUSCULAR' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Sep 2020 16:58:07 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '03 Sep 2020' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 16:58:07 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '11:24' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 16:58:07 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '03 Sep 2020 11:24' | System | 03 Sep 2020 16:58:07 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:49:36

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '03 Sep 2020' | (b) (4) Kim Calloway (b) (4) | 03 Sep 2020 16:58:23 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:36

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Kim Calloway (b) (4) | 03 Sep 2020 16:58:23 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:36

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Sep 2020 16:58:23 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:36

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '11:26' | Kim Calloway (b) (4) | 03 Sep 2020 16:58:23 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:36

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '03 Sep 2020 11:26' | System | 03 Sep 2020 16:58:23 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:36

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Kim Calloway (b) (4) | 03 Sep 2020 16:58:23 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:36

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) April Green (b) (4) | 11 Oct 2020 02:17:31 |
| User entered 'No (N)' reason for change: Data Entry Error | Kim Hamilton (b) (4) | 09 Oct 2020 15:54:10 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Sep 2020 16:58:23 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:36

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '11:26' reason for change: Data Entry Error | (b) (4) | 11 Oct 2020 02:17:31 |
| User entered empty; reason for change Data Entry Error | April Green (b) (4) | 11 Oct 2020 02:17:31 |
| | (b) (4) | |
| User entered '11:26' | Kim Hamilton (b) (4) | 09 Oct 2020 15:54:10 |
| | | |
| | Kim Calloway (b) (4) | 03 Sep 2020 16:58:23 |
| | (b) (4) | |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:36

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '03 Sep 2020 11:26' | System | 11 Oct 2020 02:17:31 |
| User entered empty. | System | 09 Oct 2020 15:54:10 |
| User entered '03 Sep 2020 11:26' | System | 03 Sep 2020 16:58:23 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 16 Sep 2020 16:18:07 |

US3452332

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered '1' | System | 16 Sep 2020 16:18:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:22:32', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bc02d20e-241e-4232-95ed-7ee32bb758cc' User entered 'Yes (Y)' | System | 03 Sep 2020 17:22:53 |
| | System | 03 Sep 2020 17:22:53 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:22:38', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bc02d20e-241e-4232-95ed-7ee32bb758cc' User entered '98.3' | System | 03 Sep 2020 17:22:53 |
| | System | 03 Sep 2020 17:22:53 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:22:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bc02d20e-241e-4232-95ed-7ee32bb758cc' User entered 'No (N)' | System | 03 Sep 2020 17:22:53 |
| | System | 03 Sep 2020 17:22:53 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:22:52', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bc02d20e-241e-4232-95ed-7ee32bb758cc' User entered '03 Sep 2020 12:22' | System | 03 Sep 2020 17:22:53 |
| | System | 03 Sep 2020 17:22:53 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Sep 2020 12:05' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Sep 2020 14:35' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:29:50', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '734c9e1d-aa27-450e-9030-ee7f7378aca4' User entered 'Yes (Y)' | System | 04 Sep 2020 11:30:21 |
| | System | 04 Sep 2020 11:30:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:29:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '734c9e1d-aa27-450e-9030-ee7f7378aca4' User entered '96.8' | System | 04 Sep 2020 11:30:21 |
| | System | 04 Sep 2020 11:30:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:30:03', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '734c9e1d-aa27-450e-9030-ee7f7378aca4' | System | 04 Sep 2020 11:30:21 |
| User entered 'No (N)' | System | 04 Sep 2020 11:30:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:30:19', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '734c9e1d-aa27-450e-9030-ee7f7378aca4' User entered '04 Sep 2020 06:30' | System | 04 Sep 2020 11:30:21 |
| | System | 04 Sep 2020 11:30:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Sep 2020 15:30' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 2' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:51:46', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '83438d8f-5eb6-467d-b444-c96df230ffab' User entered 'Yes (Y)' | System | 04 Sep 2020 22:52:24 |
| | System | 04 Sep 2020 22:52:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:52:04', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '83438d8f-5eb6-467d-b444-c96df230ffab' User entered '98.2' | System | 04 Sep 2020 22:52:24 |
| | System | 04 Sep 2020 22:52:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:52:11', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '83438d8f-5eb6-467d-b444-c96df230ffab' User entered 'No (N)' | System | 04 Sep 2020 22:52:24 |
| | System | 04 Sep 2020 22:52:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:52:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '83438d8f-5eb6-467d-b444-c96df230ffab' User entered '04 Sep 2020 17:52' | System | 04 Sep 2020 22:52:24 |
| | System | 04 Sep 2020 22:52:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 3' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:28:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b07e3ed3-1461-46ff-85c5-67328f5ee929' | System | 05 Sep 2020 20:29:23 |
| User entered 'Yes (Y)' | System | 05 Sep 2020 20:29:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:29:04', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b07e3ed3-1461-46ff-85c5-67328f5ee929' User entered '97.5' | System | 05 Sep 2020 20:29:23 |
| | System | 05 Sep 2020 20:29:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:29:11', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b07e3ed3-1461-46ff-85c5-67328f5ee929' | System | 05 Sep 2020 20:29:23 |
| User entered 'No (N)' | System | 05 Sep 2020 20:29:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:29:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b07e3ed3-1461-46ff-85c5-67328f5ee929' | System | 05 Sep 2020 20:29:23 |
| User entered '05 Sep 2020 15:29' | System | 05 Sep 2020 20:29:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 4' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:07:54', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c72f0f4c-5dad-41e7-be3b-a70af74e6c28' User entered 'Yes (Y)' | System | 06 Sep 2020 17:08:21 |
| | System | 06 Sep 2020 17:08:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:07:59', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c72f0f4c-5dad-41e7-be3b-a70af74e6c28' User entered '96.3' | System | 06 Sep 2020 17:08:21 |
| | System | 06 Sep 2020 17:08:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:08:07', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c72f0f4c-5dad-41e7-be3b-a70af74e6c28' | System | 06 Sep 2020 17:08:21 |
| User entered 'No (N)' | System | 06 Sep 2020 17:08:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:08:19', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c72f0f4c-5dad-41e7-be3b-a70af74e6c28' User entered '06 Sep 2020 12:08' | System | 06 Sep 2020 17:08:21 |
| | System | 06 Sep 2020 17:08:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 5' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:41:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0a0397b8-7ade-48a0-ba7a-25a265f8662c' User entered 'Yes (Y)' | System | 07 Sep 2020 17:41:55 |
| | System | 07 Sep 2020 17:41:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:41:30', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0a0397b8-7ade-48a0-ba7a-25a265f8662c' User entered '96.9' | System | 07 Sep 2020 17:41:55 |
| | System | 07 Sep 2020 17:41:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:41:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0a0397b8-7ade-48a0-ba7a-25a265f8662c' User entered 'No (N)' | System | 07 Sep 2020 17:41:55 |
| | System | 07 Sep 2020 17:41:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:41:54', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0a0397b8-7ade-48a0-ba7a-25a265f8662c' User entered '07 Sep 2020 12:41' | System | 07 Sep 2020 17:41:55 |
| | System | 07 Sep 2020 17:41:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 6' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:02:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4e6f48f6-07f0-4790-a4df-e925d15de5c6' User entered 'Yes (Y)' | System | 08 Sep 2020 17:04:00 |
| | System | 08 Sep 2020 17:04:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:02:24', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4e6f48f6-07f0-4790-a4df-e925d15de5c6' User entered '96.9' | System | 08 Sep 2020 17:04:00 |
| | System | 08 Sep 2020 17:04:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:02:30', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4e6f48f6-07f0-4790-a4df-e925d15de5c6' | System | 08 Sep 2020 17:04:00 |
| User entered 'No (N)' | System | 08 Sep 2020 17:04:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:02:37', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4e6f48f6-07f0-4790-a4df-e925d15de5c6' User entered '08 Sep 2020 12:02' | System | 08 Sep 2020 17:04:00 |
| | System | 08 Sep 2020 17:04:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 7' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:02:10', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '53cb2795-d8eb-428a-b79c-af8d03fdd130' User entered 'Yes (Y)' | System | 09 Sep 2020 17:03:48 |
| | System | 09 Sep 2020 17:03:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:02:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '53cb2795-d8eb-428a-b79c-af8d03fdd130' User entered '97.2' | System | 09 Sep 2020 17:03:48 |
| | System | 09 Sep 2020 17:03:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:02:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '53cb2795-d8eb-428a-b79c-af8d03fdd130' User entered 'No (N)' | System | 09 Sep 2020 17:03:48 |
| | System | 09 Sep 2020 17:03:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:02:29', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '53cb2795-d8eb-428a-b79c-af8d03fdd130' User entered '09 Sep 2020 12:02' | System | 09 Sep 2020 17:03:48 |
| | System | 09 Sep 2020 17:03:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ccc50350-702b-44d4-90b2-5591511f3bbe' User entered 'None (1)' | System | 03 Sep 2020 17:23:21 |
| | System | 03 Sep 2020 17:23:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:05', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ccc50350-702b-44d4-90b2-5591511f3bbe' User entered 'No (N)' | System | 03 Sep 2020 17:23:21 |
| | System | 03 Sep 2020 17:23:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ccc50350-702b-44d4-90b2-5591511f3bbe' User entered 'No (N)' | System | 03 Sep 2020 17:23:21 |
| | System | 03 Sep 2020 17:23:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ccc50350-702b-44d4-90b2-5591511f3bbe' User entered 'None (1)' | System | 03 Sep 2020 17:23:21 |
| | System | 03 Sep 2020 17:23:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:19', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ccc50350-702b-44d4-90b2-5591511f3bbe' User entered '03 Sep 2020 12:23' | System | 03 Sep 2020 17:23:21 |
| | System | 03 Sep 2020 17:23:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Sep 2020 12:05' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Sep 2020 14:35' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:30:50', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'deae8c6-6453-4593-8fc2-7de8ba75e9bf' | System | 04 Sep 2020 11:32:02 |
| User entered 'None (1)' | System | 04 Sep 2020 11:32:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:31:08', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'deae8c6-6453-4593-8fc2-7de8ba75e9bf' | System | 04 Sep 2020 11:32:02 |
| User entered 'No (N)' | System | 04 Sep 2020 11:32:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:31:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'deae8c6-6453-4593-8fc2-7de8ba75e9bf' | System | 04 Sep 2020 11:32:02 |
| User entered 'No (N)' | System | 04 Sep 2020 11:32:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:31:35', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'deae8c6-6453-4593-8fc2-7de8ba75e9bf' | System | 04 Sep 2020 11:32:02 |
| User entered 'None (1)' | System | 04 Sep 2020 11:32:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:31:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'deae8c6-6453-4593-8fc2-7de8ba75e9bf' User entered '04 Sep 2020 06:31' | System | 04 Sep 2020 11:32:02 |
| | System | 04 Sep 2020 11:32:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Sep 2020 15:30' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 2' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:52:37', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '46f68ddf-a5ec-4dec-ba3b-a1a22a977b55' | System | 04 Sep 2020 22:53:08 |
| User entered 'None (1)' | System | 04 Sep 2020 22:53:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:52:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '46f68ddf-a5ec-4dec-ba3b-a1a22a977b55' | System | 04 Sep 2020 22:53:08 |
| User entered 'No (N)' | System | 04 Sep 2020 22:53:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:52:47', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '46f68ddf-a5ec-4dec-ba3b-a1a22a977b55' | System | 04 Sep 2020 22:53:08 |
| User entered 'No (N)' | System | 04 Sep 2020 22:53:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:52:55', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '46f68ddf-a5ec-4dec-ba3b-a1a22a977b55' | System | 04 Sep 2020 22:53:08 |
| User entered 'None (1)' | System | 04 Sep 2020 22:53:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:53:06', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '46f68ddf-a5ec-4dec-ba3b-a1a22a977b55' User entered '04 Sep 2020 17:53' | System | 04 Sep 2020 22:53:08 |
| | System | 04 Sep 2020 22:53:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 3' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:29:28', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '23afdc3b-5cfb-460d-8495-8938de000f9d' User entered 'None (1)' | System | 05 Sep 2020 20:29:50 |
| | System | 05 Sep 2020 20:29:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:29:32', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '23afdc3b-5cfb-460d-8495-8938de000f9d' User entered 'No (N)' | System | 05 Sep 2020 20:29:50 |
| | System | 05 Sep 2020 20:29:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:29:36', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '23afdc3b-5cfb-460d-8495-8938de000f9d' User entered 'No (N)' | System | 05 Sep 2020 20:29:50 |
| | System | 05 Sep 2020 20:29:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:29:41', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '23afdc3b-5cfb-460d-8495-8938de000f9d' User entered 'None (1)' | System | 05 Sep 2020 20:29:50 |
| | System | 05 Sep 2020 20:29:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:29:47', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '23afdc3b-5cfb-460d-8495-8938de000f9d' User entered '05 Sep 2020 15:29' | System | 05 Sep 2020 20:29:50 |
| | System | 05 Sep 2020 20:29:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 4' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:08:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'aee755cb-2428-4c98-b48a-72131e2b65c9' User entered 'None (1)' | System | 06 Sep 2020 17:08:53 |
| | System | 06 Sep 2020 17:08:53 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:08:30', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'aee755cb-2428-4c98-b48a-72131e2b65c9' User entered 'No (N)' | System | 06 Sep 2020 17:08:53 |
| | System | 06 Sep 2020 17:08:53 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:08:34', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'aee755cb-2428-4c98-b48a-72131e2b65c9' User entered 'No (N)' | System | 06 Sep 2020 17:08:53 |
| | System | 06 Sep 2020 17:08:53 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:08:40', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'aee755cb-2428-4c98-b48a-72131e2b65c9' User entered 'None (1)' | System | 06 Sep 2020 17:08:53 |
| | System | 06 Sep 2020 17:08:53 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:08:50', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'aee755cb-2428-4c98-b48a-72131e2b65c9' User entered '06 Sep 2020 12:08' | System | 06 Sep 2020 17:08:53 |
| | System | 06 Sep 2020 17:08:53 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 5' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:42:02', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e6523cf9-d1e8-4680-93b6-d9e400f9403f' User entered 'None (1)' | System | 07 Sep 2020 17:42:21 |
| | System | 07 Sep 2020 17:42:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:42:06', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e6523cf9-d1e8-4680-93b6-d9e400f9403f' User entered 'No (N)' | System | 07 Sep 2020 17:42:21 |
| | System | 07 Sep 2020 17:42:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:42:10', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e6523cf9-d1e8-4680-93b6-d9e400f9403f' User entered 'No (N)' | System | 07 Sep 2020 17:42:21 |
| | System | 07 Sep 2020 17:42:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:42:14', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e6523cf9-d1e8-4680-93b6-d9e400f9403f' User entered 'None (1)' | System | 07 Sep 2020 17:42:21 |
| | System | 07 Sep 2020 17:42:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:42:18', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e6523cf9-d1e8-4680-93b6-d9e400f9403f' User entered '07 Sep 2020 12:42' | System | 07 Sep 2020 17:42:21 |
| | System | 07 Sep 2020 17:42:21 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 6' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:02:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0efa5aa2-7889-4656-933e-9cdef1205eda' User entered 'None (1)' | System | 08 Sep 2020 17:04:34 |
| | System | 08 Sep 2020 17:04:34 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:02:53', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0efa5aa2-7889-4656-933e-9cdef1205eda' User entered 'No (N)' | System | 08 Sep 2020 17:04:34 |
| | System | 08 Sep 2020 17:04:34 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:02:57', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0efa5aa2-7889-4656-933e-9cdef1205eda' User entered 'No (N)' | System | 08 Sep 2020 17:04:34 |
| | System | 08 Sep 2020 17:04:34 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:03:06', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0efa5aa2-7889-4656-933e-9cdef1205eda' User entered 'None (1)' | System | 08 Sep 2020 17:04:34 |
| | System | 08 Sep 2020 17:04:34 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:03:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0efa5aa2-7889-4656-933e-9cdef1205eda' User entered '08 Sep 2020 12:03' | System | 08 Sep 2020 17:04:34 |
| | System | 08 Sep 2020 17:04:34 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 7' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:02:34', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7745acec-0b68-4b53-8861-aa01ce6716a5' User entered 'None (1)' | System | 09 Sep 2020 17:04:00 |
| | System | 09 Sep 2020 17:04:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:02:38', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7745acec-0b68-4b53-8861-aa01ce6716a5' User entered 'No (N)' | System | 09 Sep 2020 17:04:00 |
| | System | 09 Sep 2020 17:04:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:02:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7745acec-0b68-4b53-8861-aa01ce6716a5' User entered 'No (N)' | System | 09 Sep 2020 17:04:00 |
| | System | 09 Sep 2020 17:04:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:02:46', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7745acec-0b68-4b53-8861-aa01ce6716a5' User entered 'None (1)' | System | 09 Sep 2020 17:04:00 |
| | System | 09 Sep 2020 17:04:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:02:52', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7745acec-0b68-4b53-8861-aa01ce6716a5' User entered '09 Sep 2020 12:02' | System | 09 Sep 2020 17:04:00 |
| | System | 09 Sep 2020 17:04:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:26', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '169f0b0b-85aa-4970-be73-29a229b994d0' User entered 'None (0)' | System | 03 Sep 2020 17:23:54 |
| | System | 03 Sep 2020 17:23:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:32', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '169f0b0b-85aa-4970-be73-29a229b994d0' User entered 'None (0)' | System | 03 Sep 2020 17:23:54 |
| | System | 03 Sep 2020 17:23:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:34', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '169f0b0b-85aa-4970-be73-29a229b994d0' User entered 'None (0)' | System | 03 Sep 2020 17:23:54 |
| | System | 03 Sep 2020 17:23:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:37', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '169f0b0b-85aa-4970-be73-29a229b994d0' User entered 'None (0)' | System | 03 Sep 2020 17:23:54 |
| | System | 03 Sep 2020 17:23:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '169f0b0b-85aa-4970-be73-29a229b994d0' User entered 'None (0)' | System | 03 Sep 2020 17:23:54 |
| | System | 03 Sep 2020 17:23:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '169f0b0b-85aa-4970-be73-29a229b994d0' User entered 'None (0)' | System | 03 Sep 2020 17:23:54 |
| | System | 03 Sep 2020 17:23:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '169f0b0b-85aa-4970-be73-29a229b994d0' User entered 'No (N)' | System | 03 Sep 2020 17:23:54 |
| | System | 03 Sep 2020 17:23:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-03T12:23:51', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '169f0b0b-85aa-4970-be73-29a229b994d0' User entered '03 Sep 2020 12:23' | System | 03 Sep 2020 17:23:54 |
| | System | 03 Sep 2020 17:23:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Sep 2020 12:05' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Sep 2020 14:35' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:32:28', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c74b439-630e-4251-acfa-ef05167f1ba9' | System | 04 Sep 2020 11:34:30 |
| User entered 'No interference with activity (1)' | System | 04 Sep 2020 11:34:30 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:32:41', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c74b439-630e-4251-acfa-ef05167f1ba9' | System | 04 Sep 2020 11:34:30 |
| User entered 'No interference with activity (1)' | System | 04 Sep 2020 11:34:30 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:32:52', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c74b439-630e-4251-acfa-ef05167f1ba9' User entered 'None (0)' | System | 04 Sep 2020 11:34:30 |
| | System | 04 Sep 2020 11:34:30 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:33:08', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c74b439-630e-4251-acfa-ef05167f1ba9' | System | 04 Sep 2020 11:34:30 |
| User entered 'No interference with activity (1)' | System | 04 Sep 2020 11:34:30 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:33:40', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c74b439-630e-4251-acfa-ef05167f1ba9' User entered 'None (0)' | System | 04 Sep 2020 11:34:30 |
| | System | 04 Sep 2020 11:34:30 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:33:53', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c74b439-630e-4251-acfa-ef05167f1ba9' | System | 04 Sep 2020 11:34:30 |
| User entered 'No interference with activity (1)' | System | 04 Sep 2020 11:34:30 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:34:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c74b439-630e-4251-acfa-ef05167f1ba9' User entered 'No (N)' | System | 04 Sep 2020 11:34:30 |
| | System | 04 Sep 2020 11:34:30 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T06:34:28', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c74b439-630e-4251-acfa-ef05167f1ba9' User entered '04 Sep 2020 06:34' | System | 04 Sep 2020 11:34:30 |
| | System | 04 Sep 2020 11:34:30 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Sep 2020 15:30' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 2' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:53:18', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '59328eb6-4c66-41e5-8695-9031fd7e51ab' User entered 'None (0)' | System | 04 Sep 2020 22:54:23 |
| | System | 04 Sep 2020 22:54:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:53:26', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '59328eb6-4c66-41e5-8695-9031fd7e51ab' User entered 'None (0)' | System | 04 Sep 2020 22:54:23 |
| | System | 04 Sep 2020 22:54:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:53:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '59328eb6-4c66-41e5-8695-9031fd7e51ab' User entered 'None (0)' | System | 04 Sep 2020 22:54:23 |
| | System | 04 Sep 2020 22:54:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:53:43', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '59328eb6-4c66-41e5-8695-9031fd7e51ab' User entered 'None (0)' | System | 04 Sep 2020 22:54:23 |
| | System | 04 Sep 2020 22:54:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:53:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '59328eb6-4c66-41e5-8695-9031fd7e51ab' User entered 'None (0)' | System | 04 Sep 2020 22:54:23 |
| | System | 04 Sep 2020 22:54:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:53:52', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '59328eb6-4c66-41e5-8695-9031fd7e51ab' User entered 'None (0)' | System | 04 Sep 2020 22:54:23 |
| | System | 04 Sep 2020 22:54:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:54:07', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '59328eb6-4c66-41e5-8695-9031fd7e51ab' User entered 'No (N)' | System | 04 Sep 2020 22:54:23 |
| | System | 04 Sep 2020 22:54:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-04T17:54:19', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '59328eb6-4c66-41e5-8695-9031fd7e51ab' User entered '04 Sep 2020 17:54' | System | 04 Sep 2020 22:54:23 |
| | System | 04 Sep 2020 22:54:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 3' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:29:56', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7f0f7575-e1ad-4a8f-93e5-c5111566c8db' User entered 'None (0)' | System | 05 Sep 2020 20:30:47 |
| | System | 05 Sep 2020 20:30:47 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:30:02', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7f0f7575-e1ad-4a8f-93e5-c5111566c8db' User entered 'None (0)' | System | 05 Sep 2020 20:30:47 |
| | System | 05 Sep 2020 20:30:47 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:30:05', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7f0f7575-e1ad-4a8f-93e5-c5111566c8db' User entered 'None (0)' | System | 05 Sep 2020 20:30:47 |
| | System | 05 Sep 2020 20:30:47 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:30:09', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7f0f7575-e1ad-4a8f-93e5-c5111566c8db' User entered 'None (0)' | System | 05 Sep 2020 20:30:47 |
| | System | 05 Sep 2020 20:30:47 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:30:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7f0f7575-e1ad-4a8f-93e5-c5111566c8db' User entered 'None (0)' | System | 05 Sep 2020 20:30:47 |
| | System | 05 Sep 2020 20:30:47 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:30:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7f0f7575-e1ad-4a8f-93e5-c5111566c8db' User entered 'None (0)' | System | 05 Sep 2020 20:30:47 |
| | System | 05 Sep 2020 20:30:47 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:30:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7f0f7575-e1ad-4a8f-93e5-c5111566c8db' User entered 'No (N)' | System | 05 Sep 2020 20:30:47 |
| | System | 05 Sep 2020 20:30:47 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-05T15:30:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7f0f7575-e1ad-4a8f-93e5-c5111566c8db' User entered '05 Sep 2020 15:30' | System | 05 Sep 2020 20:30:47 |
| | System | 05 Sep 2020 20:30:47 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 4' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:08:57', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5a336273-091a-4c38-87d6-d19370f723da' User entered 'None (0)' | System | 06 Sep 2020 17:10:56 |
| | System | 06 Sep 2020 17:10:56 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:09:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5a336273-091a-4c38-87d6-d19370f723da' User entered 'None (0)' | System | 06 Sep 2020 17:10:56 |
| | System | 06 Sep 2020 17:10:56 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:09:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5a336273-091a-4c38-87d6-d19370f723da' User entered 'No interference with activity (1)' | System | 06 Sep 2020 17:10:56 |
| | System | 06 Sep 2020 17:10:56 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:10:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5a336273-091a-4c38-87d6-d19370f723da' User entered 'No interference with activity (1)' | System | 06 Sep 2020 17:10:56 |
| | System | 06 Sep 2020 17:10:56 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:10:19', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5a336273-091a-4c38-87d6-d19370f723da' User entered 'None (0)' | System | 06 Sep 2020 17:10:56 |
| | System | 06 Sep 2020 17:10:56 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:10:26', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5a336273-091a-4c38-87d6-d19370f723da' User entered 'None (0)' | System | 06 Sep 2020 17:10:56 |
| | System | 06 Sep 2020 17:10:56 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:10:36', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5a336273-091a-4c38-87d6-d19370f723da' User entered 'No (N)' | System | 06 Sep 2020 17:10:56 |
| | System | 06 Sep 2020 17:10:56 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-06T12:10:55', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5a336273-091a-4c38-87d6-d19370f723da' User entered '06 Sep 2020 12:10' | System | 06 Sep 2020 17:10:56 |
| | System | 06 Sep 2020 17:10:56 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 5' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:42:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e13d520b-159d-4f1d-86a0-66e9a95fdf75' User entered 'None (0)' | System | 07 Sep 2020 17:43:29 |
| | System | 07 Sep 2020 17:43:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:42:45', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e13d520b-159d-4f1d-86a0-66e9a95fdf75' User entered 'None (0)' | System | 07 Sep 2020 17:43:29 |
| | System | 07 Sep 2020 17:43:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:43:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e13d520b-159d-4f1d-86a0-66e9a95fdf75' | System | 07 Sep 2020 17:43:29 |
| User entered 'No interference with activity (1)' | System | 07 Sep 2020 17:43:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:43:07', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e13d520b-159d-4f1d-86a0-66e9a95fdf75' | System | 07 Sep 2020 17:43:29 |
| User entered 'No interference with activity (1)' | System | 07 Sep 2020 17:43:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:43:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e13d520b-159d-4f1d-86a0-66e9a95fdf75' User entered 'None (0)' | System | 07 Sep 2020 17:43:29 |
| | System | 07 Sep 2020 17:43:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:43:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e13d520b-159d-4f1d-86a0-66e9a95fdf75' User entered 'None (0)' | System | 07 Sep 2020 17:43:29 |
| | System | 07 Sep 2020 17:43:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:43:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e13d520b-159d-4f1d-86a0-66e9a95fdf75' User entered 'No (N)' | System | 07 Sep 2020 17:43:29 |
| | System | 07 Sep 2020 17:43:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-07T12:43:26', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e13d520b-159d-4f1d-86a0-66e9a95fdf75' User entered '07 Sep 2020 12:43' | System | 07 Sep 2020 17:43:29 |
| | System | 07 Sep 2020 17:43:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 6' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:03:32', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '54287725-614a-4d69-af97-e5855909274a' | System | 08 Sep 2020 17:05:13 |
| User entered 'No interference with activity (1)' | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:03:35', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '54287725-614a-4d69-af97-e5855909274a' User entered 'None (0)' | System | 08 Sep 2020 17:05:13 |
| | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:03:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '54287725-614a-4d69-af97-e5855909274a' | System | 08 Sep 2020 17:05:13 |
| User entered 'No interference with activity (1)' | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:03:45', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '54287725-614a-4d69-af97-e5855909274a' User entered 'No interference with activity (1)' | System | 08 Sep 2020 17:05:13 |
| | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:03:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '54287725-614a-4d69-af97-e5855909274a' User entered 'None (0)' | System | 08 Sep 2020 17:05:13 |
| | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:03:53', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '54287725-614a-4d69-af97-e5855909274a' User entered 'None (0)' | System | 08 Sep 2020 17:05:13 |
| | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:04:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '54287725-614a-4d69-af97-e5855909274a' User entered 'No (N)' | System | 08 Sep 2020 17:05:13 |
| | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-08T12:04:11', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '54287725-614a-4d69-af97-e5855909274a' User entered '08 Sep 2020 12:04' | System | 08 Sep 2020 17:05:13 |
| | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Sep 2020 16:57:52 |
| User entered 'Day 7' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:03:07', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b80e62d4-0574-4826-9262-c7d8825b452f' User entered 'None (0)' | System | 09 Sep 2020 17:05:02 |
| | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:03:10', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b80e62d4-0574-4826-9262-c7d8825b452f' User entered 'None (0)' | System | 09 Sep 2020 17:05:02 |
| | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:03:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b80e62d4-0574-4826-9262-c7d8825b452f' | System | 09 Sep 2020 17:05:02 |
| User entered 'No interference with activity (1)' | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:03:26', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b80e62d4-0574-4826-9262-c7d8825b452f' | System | 09 Sep 2020 17:05:02 |
| User entered 'No interference with activity (1)' | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:03:31', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b80e62d4-0574-4826-9262-c7d8825b452f' User entered 'None (0)' | System | 09 Sep 2020 17:05:02 |
| | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:03:34', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b80e62d4-0574-4826-9262-c7d8825b452f' User entered 'None (0)' | System | 09 Sep 2020 17:05:02 |
| | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:03:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b80e62d4-0574-4826-9262-c7d8825b452f' User entered 'No (N)' | System | 09 Sep 2020 17:05:02 |
| | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-09T12:03:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b80e62d4-0574-4826-9262-c7d8825b452f' User entered '09 Sep 2020 12:03' | System | 09 Sep 2020 17:05:02 |
| | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Sep 2020 12:00' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Sep 2020 11:59' | System | 03 Sep 2020 16:57:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 08 Sep 2020 17:05:13 |
| User entered 'Day 8' | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-10T12:00:55', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6505d43c-6b43-497b-a38a-f0c57567a436' | System | 10 Sep 2020 17:01:20 |
| User entered 'No interference with activity (1)' | System | 10 Sep 2020 17:01:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-10T12:01:07', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6505d43c-6b43-497b-a38a-f0c57567a436' User entered '10 Sep 2020 12:01' | System | 10 Sep 2020 17:01:20 |
| | System | 10 Sep 2020 17:01:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 09 Sep 2020 17:05:02 |
| User entered 'Day 9' | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-11T14:02:15', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ecc42cf5-0879-4147-bfce-a482c2062fe8' | System | 11 Sep 2020 19:02:29 |
| User entered 'No interference with activity (1)' | System | 11 Sep 2020 19:02:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-11T14:02:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ecc42cf5-0879-4147-bfce-a482c2062fe8' User entered '11 Sep 2020 14:02' | System | 11 Sep 2020 19:02:29 |
| | System | 11 Sep 2020 19:02:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Sep 2020 12:00' | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Sep 2020 11:59' | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 10 Sep 2020 17:01:20 |
| User entered 'Day 10' | System | 10 Sep 2020 17:01:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-12T12:23:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'da70ed6a-3754-496f-987a-5a427c09b597' | System | 12 Sep 2020 17:23:52 |
| User entered 'No interference with activity (1)' | System | 12 Sep 2020 17:23:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-12T12:23:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'da70ed6a-3754-496f-987a-5a427c09b597' User entered '12 Sep 2020 12:23' | System | 12 Sep 2020 17:23:52 |
| | System | 12 Sep 2020 17:23:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Sep 2020 12:00' | System | 10 Sep 2020 17:01:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Sep 2020 11:59' | System | 10 Sep 2020 17:01:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 11 Sep 2020 19:02:29 |
| User entered 'Day 11' | System | 11 Sep 2020 19:02:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-13T22:17:03', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '56cfda2a-44ff-4b77-921e-ec23cc518311' User entered 'No interference with activity (1)' | System | 14 Sep 2020 03:17:10 |
| | System | 14 Sep 2020 03:17:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-13T22:17:07', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '56cfda2a-44ff-4b77-921e-ec23cc518311' User entered '13 Sep 2020 22:17' | System | 14 Sep 2020 03:17:10 |
| | System | 14 Sep 2020 03:17:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Sep 2020 12:00' | System | 11 Sep 2020 19:02:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Sep 2020 11:59' | System | 11 Sep 2020 19:02:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 12 Sep 2020 17:23:52 |
| User entered 'Day 12' | System | 12 Sep 2020 17:23:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-14T14:30:55', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '44eeac43-9494-44df-ac6c-c2525db790a4' | System | 14 Sep 2020 19:31:04 |
| User entered 'No interference with activity (1)' | System | 14 Sep 2020 19:31:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-14T14:30:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '44eeac43-9494-44df-ac6c-c2525db790a4' User entered '14 Sep 2020 14:30' | System | 14 Sep 2020 19:31:04 |
| | System | 14 Sep 2020 19:31:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Sep 2020 12:00' | System | 12 Sep 2020 17:23:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Sep 2020 11:59' | System | 12 Sep 2020 17:23:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 14 Sep 2020 03:17:10 |
| User entered 'Day 13' | System | 14 Sep 2020 03:17:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-15T12:02:11', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7d694f3b-dd0d-42f7-80e8-2eeba59bb339' | System | 15 Sep 2020 17:03:25 |
| User entered 'Some interference with activity (2)' | System | 15 Sep 2020 17:03:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-15T12:02:14', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7d694f3b-dd0d-42f7-80e8-2eeba59bb339' User entered '15 Sep 2020 12:02' | System | 15 Sep 2020 17:03:25 |
| | System | 15 Sep 2020 17:03:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Sep 2020 12:00' | System | 14 Sep 2020 03:17:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Sep 2020 11:59' | System | 14 Sep 2020 03:17:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 14 Sep 2020 19:31:04 |
| User entered 'Day 14' | System | 14 Sep 2020 19:31:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-16T12:22:19', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8c8ae7e6-d2c7-419e-b576-f5723e37851b' User entered 'No interference with activity (1)' | System | 16 Sep 2020 17:22:23 |
| | System | 16 Sep 2020 17:22:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-16T12:22:22', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8c8ae7e6-d2c7-419e-b576-f5723e37851b' User entered '16 Sep 2020 12:22' | System | 16 Sep 2020 17:22:23 |
| | System | 16 Sep 2020 17:22:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Sep 2020 12:00' | System | 14 Sep 2020 19:31:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Sep 2020 11:59' | System | 14 Sep 2020 19:31:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 15 Sep 2020 17:03:25 |
| User entered 'Day 15' | System | 15 Sep 2020 17:03:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-17T12:04:11', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2d940cca-d7e1-4e1b-a71b-7a64b8eed37c' | System | 17 Sep 2020 17:05:05 |
| User entered 'No interference with activity (1)' | System | 17 Sep 2020 17:05:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-17T12:04:14', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2d940cca-d7e1-4e1b-a71b-7a64b8eed37c' User entered '17 Sep 2020 12:04' | System | 17 Sep 2020 17:05:05 |
| | System | 17 Sep 2020 17:05:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 17:03:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 17:03:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 16 Sep 2020 17:22:23 |
| User entered 'Day 16' | System | 16 Sep 2020 17:22:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-18T12:12:05', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c38a1b22-a815-47fb-9425-0f75f3102c74' | System | 18 Sep 2020 17:12:14 |
| User entered 'No interference with activity (1)' | System | 18 Sep 2020 17:12:14 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-18T12:12:09', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c38a1b22-a815-47fb-9425-0f75f3102c74' User entered '18 Sep 2020 12:12' | System | 18 Sep 2020 17:12:14 |
| | System | 18 Sep 2020 17:12:14 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 17:22:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 17:22:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 17 Sep 2020 17:05:05 |
| User entered 'Day 17' | System | 17 Sep 2020 17:05:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-19T14:27:37', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b237b408-5131-46f8-bb5f-85cad5455420' | System | 19 Sep 2020 19:27:46 |
| User entered 'No interference with activity (1)' | System | 19 Sep 2020 19:27:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-19T14:27:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b237b408-5131-46f8-bb5f-85cad5455420' User entered '19 Sep 2020 14:27' | System | 19 Sep 2020 19:27:46 |
| | System | 19 Sep 2020 19:27:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 17:05:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 17:05:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 18 Sep 2020 17:12:14 |
| User entered 'Day 18' | System | 18 Sep 2020 17:12:14 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-20T12:16:04', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'db85ccb5-4405-414f-a632-b31678184782' | System | 20 Sep 2020 17:16:16 |
| User entered 'No interference with activity (1)' | System | 20 Sep 2020 17:16:16 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-20T12:16:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'db85ccb5-4405-414f-a632-b31678184782' User entered '20 Sep 2020 12:16' | System | 20 Sep 2020 17:16:16 |
| | System | 20 Sep 2020 17:16:16 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Sep 2020 12:00' | System | 18 Sep 2020 17:12:14 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Sep 2020 11:59' | System | 18 Sep 2020 17:12:14 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 19 Sep 2020 19:27:46 |
| User entered 'Day 19' | System | 19 Sep 2020 19:27:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-21T12:02:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '91d65e3f-1f1c-4ba3-9e21-1fbdabee8a8e' User entered 'No interference with activity (1)' | System | 21 Sep 2020 17:05:13 |
| | System | 21 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-21T12:02:04', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '91d65e3f-1f1c-4ba3-9e21-1fbdabee8a8e' User entered '21 Sep 2020 12:02' | System | 21 Sep 2020 17:05:13 |
| | System | 21 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Sep 2020 12:00' | System | 19 Sep 2020 19:27:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Sep 2020 11:59' | System | 19 Sep 2020 19:27:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 20 Sep 2020 17:16:16 |
| User entered 'Day 20' | System | 20 Sep 2020 17:16:16 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-22T12:00:43', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '99317935-c20c-4c76-a2a0-e8e1ac18bd46' User entered 'No interference with activity (1)' | System | 22 Sep 2020 17:01:24 |
| | System | 22 Sep 2020 17:01:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-22T12:00:46', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '99317935-c20c-4c76-a2a0-e8e1ac18bd46' User entered '22 Sep 2020 12:00' | System | 22 Sep 2020 17:01:24 |
| | System | 22 Sep 2020 17:01:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Sep 2020 12:00' | System | 20 Sep 2020 17:16:16 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Sep 2020 11:59' | System | 20 Sep 2020 17:16:16 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 21 Sep 2020 17:05:13 |
| User entered 'Day 21' | System | 21 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-23T12:30:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'af7106a5-7837-4a69-bf64-847ec3dcd1d7' | System | 23 Sep 2020 17:30:32 |
| User entered 'No interference with activity (1)' | System | 23 Sep 2020 17:30:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-23T12:30:30', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'af7106a5-7837-4a69-bf64-847ec3dcd1d7' | System | 23 Sep 2020 17:30:32 |
| User entered '23 Sep 2020 12:30' | System | 23 Sep 2020 17:30:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 22 Sep 2020 17:01:24 |
| User entered 'Day 22' | System | 22 Sep 2020 17:01:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-24T13:25:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '96d03218-24d2-4d78-9a29-04d23139e89c' | System | 24 Sep 2020 18:25:38 |
| User entered 'No interference with activity (1)' | System | 24 Sep 2020 18:25:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-24T13:25:31', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '96d03218-24d2-4d78-9a29-04d23139e89c' | System | 24 Sep 2020 18:25:38 |
| User entered '24 Sep 2020 13:25' | System | 24 Sep 2020 18:25:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Sep 2020 12:00' | System | 22 Sep 2020 17:01:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '25 Sep 2020 11:59' | System | 22 Sep 2020 17:01:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 23 Sep 2020 17:30:32 |
| User entered 'Day 23' | System | 23 Sep 2020 17:30:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-25T12:06:54', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b94193e9-34e3-428f-ba2b-e2793aaa7e2c' | System | 25 Sep 2020 17:06:59 |
| User entered 'No interference with activity (1)' | System | 25 Sep 2020 17:06:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-25T12:06:57', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b94193e9-34e3-428f-ba2b-e2793aaa7e2c' User entered '25 Sep 2020 12:06' | System | 25 Sep 2020 17:06:59 |
| | System | 25 Sep 2020 17:06:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '25 Sep 2020 12:00' | System | 23 Sep 2020 17:30:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '26 Sep 2020 11:59' | System | 23 Sep 2020 17:30:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 24 Sep 2020 18:25:38 |
| User entered 'Day 24' | System | 24 Sep 2020 18:25:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-26T14:17:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '23d5a63d-6755-471b-925d-e7b53ef5c755' | System | 26 Sep 2020 19:17:08 |
| User entered 'No interference with activity (1)' | System | 26 Sep 2020 19:17:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-26T14:17:04', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '23d5a63d-6755-471b-925d-e7b53ef5c755' User entered '26 Sep 2020 14:17' | System | 26 Sep 2020 19:17:08 |
| | System | 26 Sep 2020 19:17:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '26 Sep 2020 12:00' | System | 24 Sep 2020 18:25:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '27 Sep 2020 11:59' | System | 24 Sep 2020 18:25:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 25 Sep 2020 17:06:59 |
| User entered 'Day 25' | System | 25 Sep 2020 17:06:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-27T12:04:02', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '18c57548-5f06-4077-83f9-41a45ddf9f7c' | System | 27 Sep 2020 17:04:10 |
| User entered 'No interference with activity (1)' | System | 27 Sep 2020 17:04:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-27T12:04:09', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '18c57548-5f06-4077-83f9-41a45ddf9f7c' User entered '27 Sep 2020 12:04' | System | 27 Sep 2020 17:04:10 |
| | System | 27 Sep 2020 17:04:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '27 Sep 2020 12:00' | System | 25 Sep 2020 17:06:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '28 Sep 2020 11:59' | System | 25 Sep 2020 17:06:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 26 Sep 2020 19:17:08 |
| User entered 'Day 26' | System | 26 Sep 2020 19:17:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-28T12:28:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8281c796-310b-4353-bc2d-8c542943aa21' | System | 28 Sep 2020 17:28:22 |
| User entered 'No interference with activity (1)' | System | 28 Sep 2020 17:28:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-28T12:28:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8281c796-310b-4353-bc2d-8c542943aa21' User entered '28 Sep 2020 12:28' | System | 28 Sep 2020 17:28:22 |
| | System | 28 Sep 2020 17:28:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '28 Sep 2020 12:00' | System | 26 Sep 2020 19:17:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '29 Sep 2020 11:59' | System | 26 Sep 2020 19:17:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 27 Sep 2020 17:04:10 |
| User entered 'Day 27' | System | 27 Sep 2020 17:04:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-29T13:42:45', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c1a8b10-726c-4b03-ae51-e8a42e6eeb90' | System | 29 Sep 2020 18:42:51 |
| User entered 'No interference with activity (1)' | System | 29 Sep 2020 18:42:51 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-29T13:42:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c1a8b10-726c-4b03-ae51-e8a42e6eeb90' User entered '29 Sep 2020 13:42' | System | 29 Sep 2020 18:42:51 |
| | System | 29 Sep 2020 18:42:51 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '29 Sep 2020 12:00' | System | 27 Sep 2020 17:04:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '30 Sep 2020 11:59' | System | 27 Sep 2020 17:04:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 28 Sep 2020 17:28:22 |
| User entered 'Day 28' | System | 28 Sep 2020 17:28:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-30T13:12:59', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5f6b8fdb-3980-4de3-ab19-e3c6583c2273' | System | 30 Sep 2020 18:13:05 |
| User entered 'No interference with activity (1)' | System | 30 Sep 2020 18:13:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-30T13:13:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5f6b8fdb-3980-4de3-ab19-e3c6583c2273' User entered '30 Sep 2020 13:13' | System | 30 Sep 2020 18:13:05 |
| | System | 30 Sep 2020 18:13:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 17:28:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 17:28:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 29 Sep 2020 18:42:51 |
| User entered 'Day 29' | System | 29 Sep 2020 18:42:51 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-01T12:00:43', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '90d4f16a-dcdd-4ae5-9221-a58a48aa523d' | System | 01 Oct 2020 17:00:58 |
| User entered 'No interference with activity (1)' | System | 01 Oct 2020 17:00:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-01T12:00:46', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '90d4f16a-dcdd-4ae5-9221-a58a48aa523d' User entered '01 Oct 2020 12:00' | System | 01 Oct 2020 17:00:58 |
| | System | 01 Oct 2020 17:00:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '01 Oct 2020 12:00' | System | 29 Sep 2020 18:42:51 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '02 Oct 2020 11:59' | System | 29 Sep 2020 18:42:51 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 30 Sep 2020 18:13:05 |
| User entered 'Day 30' | System | 30 Sep 2020 18:13:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-02T12:22:51', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '50d7c5b3-3d93-483a-843b-b42e5adb3306' | System | 02 Oct 2020 17:22:57 |
| User entered 'No interference with activity (1)' | System | 02 Oct 2020 17:22:57 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-02T12:22:55', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '50d7c5b3-3d93-483a-843b-b42e5adb3306' User entered '02 Oct 2020 12:22' | System | 02 Oct 2020 17:22:57 |
| | System | 02 Oct 2020 17:22:57 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '02 Oct 2020 12:00' | System | 30 Sep 2020 18:13:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Oct 2020 11:59' | System | 30 Sep 2020 18:13:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 01 Oct 2020 17:00:58 |
| User entered 'Day 31' | System | 01 Oct 2020 17:00:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-03T12:47:38', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ff0852c7-f5c9-44f4-ba82-35af04a96e1b' | System | 03 Oct 2020 17:47:42 |
| User entered 'No interference with activity (1)' | System | 03 Oct 2020 17:47:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-03T12:47:40', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ff0852c7-f5c9-44f4-ba82-35af04a96e1b' User entered '03 Oct 2020 12:47' | System | 03 Oct 2020 17:47:42 |
| | System | 03 Oct 2020 17:47:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Oct 2020 12:00' | System | 01 Oct 2020 17:00:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Oct 2020 11:59' | System | 01 Oct 2020 17:00:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 02 Oct 2020 17:22:57 |
| User entered 'Day 32' | System | 02 Oct 2020 17:22:57 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-04T13:14:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c2b2fe81-420e-4f53-b2e0-0f33d7fd1c32' | System | 04 Oct 2020 18:14:33 |
| User entered 'No interference with activity (1)' | System | 04 Oct 2020 18:14:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-04T13:14:30', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c2b2fe81-420e-4f53-b2e0-0f33d7fd1c32' | System | 04 Oct 2020 18:14:33 |
| User entered '04 Oct 2020 13:14' | System | 04 Oct 2020 18:14:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Oct 2020 12:00' | System | 02 Oct 2020 17:22:57 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Oct 2020 11:59' | System | 02 Oct 2020 17:22:57 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Oct 2020 17:47:42 |
| User entered 'Day 33' | System | 03 Oct 2020 17:47:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-05T12:00:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '257c1129-cc81-49a3-8864-004097eccfc9' | System | 05 Oct 2020 17:00:31 |
| User entered 'No interference with activity (1)' | System | 05 Oct 2020 17:00:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-05T12:00:26', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '257c1129-cc81-49a3-8864-004097eccfc9' User entered '05 Oct 2020 12:00' | System | 05 Oct 2020 17:00:31 |
| | System | 05 Oct 2020 17:00:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Oct 2020 12:00' | System | 03 Oct 2020 17:47:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Oct 2020 11:59' | System | 03 Oct 2020 17:47:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 04 Oct 2020 18:14:33 |
| User entered 'Day 34' | System | 04 Oct 2020 18:14:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-06T12:22:47', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '86343baf-d70a-4d4f-8148-5c1ea45d057c' | System | 06 Oct 2020 17:22:52 |
| User entered 'No interference with activity (1)' | System | 06 Oct 2020 17:22:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-06T12:22:50', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '86343baf-d70a-4d4f-8148-5c1ea45d057c' User entered '06 Oct 2020 12:22' | System | 06 Oct 2020 17:22:52 |
| | System | 06 Oct 2020 17:22:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Oct 2020 12:00' | System | 04 Oct 2020 18:14:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Oct 2020 11:59' | System | 04 Oct 2020 18:14:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 05 Oct 2020 17:00:31 |
| User entered 'Day 35' | System | 05 Oct 2020 17:00:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-07T12:00:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '22a66b6c-3013-42bc-9800-696194866224' | System | 07 Oct 2020 17:00:43 |
| User entered 'No interference with activity (1)' | System | 07 Oct 2020 17:00:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-07T12:00:31', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '22a66b6c-3013-42bc-9800-696194866224' User entered '07 Oct 2020 12:00' | System | 07 Oct 2020 17:00:43 |
| | System | 07 Oct 2020 17:00:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Oct 2020 12:00' | System | 05 Oct 2020 17:00:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Oct 2020 11:59' | System | 05 Oct 2020 17:00:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 06 Oct 2020 17:22:52 |
| User entered 'Day 36' | System | 06 Oct 2020 17:22:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-08T14:01:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '940fad2d-cf48-4ecc-8fd0-75c13cc08c73' | System | 08 Oct 2020 19:01:23 |
| User entered 'No interference with activity (1)' | System | 08 Oct 2020 19:01:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-08T14:01:18', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '940fad2d-cf48-4ecc-8fd0-75c13cc08c73' User entered '08 Oct 2020 14:01' | System | 08 Oct 2020 19:01:23 |
| | System | 08 Oct 2020 19:01:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Oct 2020 12:00' | System | 06 Oct 2020 17:22:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Oct 2020 11:59' | System | 06 Oct 2020 17:22:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Oct 2020 17:00:43 |
| User entered 'Day 37' | System | 07 Oct 2020 17:00:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-09T12:00:25', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f92fc58e-0306-4e88-9293-6eec5345626d' | System | 09 Oct 2020 17:00:33 |
| User entered 'No interference with activity (1)' | System | 09 Oct 2020 17:00:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-09T12:00:28', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f92fc58e-0306-4e88-9293-6eec5345626d' User entered '09 Oct 2020 12:00' | System | 09 Oct 2020 17:00:33 |
| | System | 09 Oct 2020 17:00:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Oct 2020 12:00' | System | 07 Oct 2020 17:00:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Oct 2020 11:59' | System | 07 Oct 2020 17:00:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 08 Oct 2020 19:01:23 |
| User entered 'Day 38' | System | 08 Oct 2020 19:01:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-10T12:20:04', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '53555561-e710-4d5d-8032-e692f0c75ac7' | System | 10 Oct 2020 17:20:11 |
| User entered 'No interference with activity (1)' | System | 10 Oct 2020 17:20:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-10T12:20:08', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '53555561-e710-4d5d-8032-e692f0c75ac7' User entered '10 Oct 2020 12:20' | System | 10 Oct 2020 17:20:11 |
| | System | 10 Oct 2020 17:20:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Oct 2020 12:00' | System | 08 Oct 2020 19:01:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Oct 2020 11:59' | System | 08 Oct 2020 19:01:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 09 Oct 2020 17:00:33 |
| User entered 'Day 39' | System | 09 Oct 2020 17:00:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-11T15:35:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9c88a613-48fa-474d-8f06-a52f0911aa93' | System | 11 Oct 2020 20:35:18 |
| User entered 'No interference with activity (1)' | System | 11 Oct 2020 20:35:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-11T15:35:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9c88a613-48fa-474d-8f06-a52f0911aa93' | System | 11 Oct 2020 20:35:18 |
| User entered '11 Oct 2020 15:35' | System | 11 Oct 2020 20:35:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Oct 2020 12:00' | System | 09 Oct 2020 17:00:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Oct 2020 11:59' | System | 09 Oct 2020 17:00:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 10 Oct 2020 17:20:11 |
| User entered 'Day 40' | System | 10 Oct 2020 17:20:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-12T12:01:03', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '59f2af3f-15d6-4852-96e6-eb4b1b7209f5' | System | 12 Oct 2020 17:02:07 |
| User entered 'No interference with activity (1)' | System | 12 Oct 2020 17:02:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-12T12:01:05', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '59f2af3f-15d6-4852-96e6-eb4b1b7209f5' User entered '12 Oct 2020 12:01' | System | 12 Oct 2020 17:02:07 |
| | System | 12 Oct 2020 17:02:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Oct 2020 12:00' | System | 10 Oct 2020 17:20:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Oct 2020 11:59' | System | 10 Oct 2020 17:20:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 11 Oct 2020 20:35:18 |
| User entered 'Day 41' | System | 11 Oct 2020 20:35:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-13T12:01:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f2c687ba-9378-4056-9dc3-6240b5568c80' | System | 13 Oct 2020 17:01:48 |
| User entered 'No interference with activity (1)' | System | 13 Oct 2020 17:01:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-13T12:01:46', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f2c687ba-9378-4056-9dc3-6240b5568c80' User entered '13 Oct 2020 12:01' | System | 13 Oct 2020 17:01:48 |
| | System | 13 Oct 2020 17:01:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Oct 2020 12:00' | System | 11 Oct 2020 20:35:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Oct 2020 11:59' | System | 11 Oct 2020 20:35:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 12 Oct 2020 17:02:07 |
| User entered 'Day 42' | System | 12 Oct 2020 17:02:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T14:40:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '664c36c3-e588-4953-95b3-b2f54499f514' | System | 14 Oct 2020 19:40:39 |
| User entered 'No interference with activity (1)' | System | 14 Oct 2020 19:40:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T14:40:36', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '664c36c3-e588-4953-95b3-b2f54499f514' User entered '14 Oct 2020 14:40' | System | 14 Oct 2020 19:40:39 |
| | System | 14 Oct 2020 19:40:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Oct 2020 12:00' | System | 12 Oct 2020 17:02:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Oct 2020 11:59' | System | 12 Oct 2020 17:02:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 13 Oct 2020 17:01:48 |
| User entered 'Day 43' | System | 13 Oct 2020 17:01:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-15T12:01:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2cb043db-fa11-4e4e-9940-088e4fd0b3e3' | System | 15 Oct 2020 17:01:42 |
| User entered 'Some interference with activity (2)' | System | 15 Oct 2020 17:01:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-15T12:01:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2cb043db-fa11-4e4e-9940-088e4fd0b3e3' User entered '15 Oct 2020 12:01' | System | 15 Oct 2020 17:01:42 |
| | System | 15 Oct 2020 17:01:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Oct 2020 12:00' | System | 13 Oct 2020 17:01:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Oct 2020 11:59' | System | 13 Oct 2020 17:01:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 14 Oct 2020 19:40:39 |
| User entered 'Day 44' | System | 14 Oct 2020 19:40:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-16T13:16:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b3488bb1-5f00-4f9d-a4e5-7007ab5ea236' | System | 16 Oct 2020 18:16:32 |
| User entered 'No interference with activity (1)' | System | 16 Oct 2020 18:16:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-16T13:16:30', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b3488bb1-5f00-4f9d-a4e5-7007ab5ea236' User entered '16 Oct 2020 13:16' | System | 16 Oct 2020 18:16:32 |
| | System | 16 Oct 2020 18:16:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Oct 2020 12:00' | System | 14 Oct 2020 19:40:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Oct 2020 11:59' | System | 14 Oct 2020 19:40:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 15 Oct 2020 17:01:42 |
| User entered 'Day 45' | System | 15 Oct 2020 17:01:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-17T12:00:56', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'eb86b314-2eb4-4ea5-b332-468a9b94cf4c' | System | 17 Oct 2020 17:01:04 |
| User entered 'No interference with activity (1)' | System | 17 Oct 2020 17:01:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-17T12:00:59', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'eb86b314-2eb4-4ea5-b332-468a9b94cf4c' User entered '17 Oct 2020 12:00' | System | 17 Oct 2020 17:01:04 |
| | System | 17 Oct 2020 17:01:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Oct 2020 12:00' | System | 15 Oct 2020 17:01:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Oct 2020 11:59' | System | 15 Oct 2020 17:01:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 16 Oct 2020 18:16:32 |
| User entered 'Day 46' | System | 16 Oct 2020 18:16:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-18T12:28:22', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'cccd7f1e-bbf6-4266-836d-9a2b3187abcf' User entered 'No interference with activity (1)' | System | 18 Oct 2020 17:28:27 |
| | System | 18 Oct 2020 17:28:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-18T12:28:25', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'cccd7f1e-bbf6-4266-836d-9a2b3187abcf' User entered '18 Oct 2020 12:28' | System | 18 Oct 2020 17:28:27 |
| | System | 18 Oct 2020 17:28:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Oct 2020 12:00' | System | 16 Oct 2020 18:16:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Oct 2020 11:59' | System | 16 Oct 2020 18:16:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 17 Oct 2020 17:01:04 |
| User entered 'Day 47' | System | 17 Oct 2020 17:01:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-19T12:46:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f575c2f6-a64f-4827-97f0-4c22a3b68ccf' | System | 19 Oct 2020 17:52:50 |
| User entered 'No interference with activity (1)' | System | 19 Oct 2020 17:52:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-19T12:46:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f575c2f6-a64f-4827-97f0-4c22a3b68ccf' User entered '19 Oct 2020 12:46' | System | 19 Oct 2020 17:52:50 |
| | System | 19 Oct 2020 17:52:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Oct 2020 12:00' | System | 17 Oct 2020 17:01:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Oct 2020 11:59' | System | 17 Oct 2020 17:01:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 18 Oct 2020 17:28:27 |
| User entered 'Day 48' | System | 18 Oct 2020 17:28:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-21T08:50:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ec97fafb-1852-4fa3-9356-da8f9ab9eae3' | System | 21 Oct 2020 13:50:27 |
| User entered 'Some interference with activity (2)' | System | 21 Oct 2020 13:50:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-21T08:50:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ec97fafb-1852-4fa3-9356-da8f9ab9eae3' User entered '21 Oct 2020 08:50' | System | 21 Oct 2020 13:50:27 |
| | System | 21 Oct 2020 13:50:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Oct 2020 12:00' | System | 18 Oct 2020 17:28:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Oct 2020 11:59' | System | 18 Oct 2020 17:28:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 19 Oct 2020 17:52:50 |
| User entered 'Day 49' | System | 19 Oct 2020 17:52:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T09:02:55', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'd9ed383a-2e89-4a9f-9f6f-0ad70d0df0ee' | System | 22 Oct 2020 14:03:03 |
| User entered 'No interference with activity (1)' | System | 22 Oct 2020 14:03:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T09:02:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'd9ed383a-2e89-4a9f-9f6f-0ad70d0df0ee' User entered '22 Oct 2020 09:02' | System | 22 Oct 2020 14:03:03 |
| | System | 22 Oct 2020 14:03:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Oct 2020 12:00' | System | 19 Oct 2020 17:52:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Oct 2020 11:59' | System | 19 Oct 2020 17:52:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 21 Oct 2020 13:50:27 |
| User entered 'Day 50' | System | 21 Oct 2020 13:50:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T12:48:30', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2ead6488-2904-4617-a9d8-0470dcd82ae4' | System | 22 Oct 2020 17:48:39 |
| User entered 'No interference with activity (1)' | System | 22 Oct 2020 17:48:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T12:48:34', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2ead6488-2904-4617-a9d8-0470dcd82ae4' User entered '22 Oct 2020 12:48' | System | 22 Oct 2020 17:48:39 |
| | System | 22 Oct 2020 17:48:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Oct 2020 12:00' | System | 21 Oct 2020 13:50:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Oct 2020 11:59' | System | 21 Oct 2020 13:50:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 22 Oct 2020 14:03:03 |
| User entered 'Day 51' | System | 22 Oct 2020 14:03:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Oct 2020 12:00' | System | 22 Oct 2020 14:03:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Oct 2020 11:59' | System | 22 Oct 2020 14:03:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 22 Oct 2020 17:48:39 |
| User entered 'Day 52' | System | 22 Oct 2020 17:48:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Oct 2020 12:00' | System | 22 Oct 2020 17:48:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '25 Oct 2020 11:59' | System | 22 Oct 2020 17:48:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 08 Sep 2020 17:05:13 |
| User entered 'Day 8' | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-10T12:01:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c880dd03-eeb7-4399-a85c-06cc6d726433' | System | 10 Sep 2020 17:01:43 |
| User entered 'No interference with activity (1)' | System | 10 Sep 2020 17:01:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-10T12:01:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c880dd03-eeb7-4399-a85c-06cc6d726433' User entered '10 Sep 2020 12:01' | System | 10 Sep 2020 17:01:43 |
| | System | 10 Sep 2020 17:01:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 09 Sep 2020 17:05:02 |
| User entered 'Day 9' | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-11T14:02:32', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'd235b943-3067-414b-ba14-467c0c509534' | System | 11 Sep 2020 19:02:40 |
| User entered 'No interference with activity (1)' | System | 11 Sep 2020 19:02:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-11T14:02:36', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'd235b943-3067-414b-ba14-467c0c509534' User entered '11 Sep 2020 14:02' | System | 11 Sep 2020 19:02:40 |
| | System | 11 Sep 2020 19:02:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Sep 2020 12:00' | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Sep 2020 11:59' | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 10 Sep 2020 17:01:43 |
| User entered 'Day 10' | System | 10 Sep 2020 17:01:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-12T12:23:52', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2dc8d97b-cab2-4872-a7da-fae6c00023f2' | System | 12 Sep 2020 17:23:59 |
| User entered 'No interference with activity (1)' | System | 12 Sep 2020 17:23:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-12T12:23:56', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2dc8d97b-cab2-4872-a7da-fae6c00023f2' | System | 12 Sep 2020 17:23:59 |
| User entered '12 Sep 2020 12:23' | System | 12 Sep 2020 17:23:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Sep 2020 12:00' | System | 10 Sep 2020 17:01:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Sep 2020 11:59' | System | 10 Sep 2020 17:01:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 11 Sep 2020 19:02:40 |
| User entered 'Day 11' | System | 11 Sep 2020 19:02:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-13T22:17:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '12c9fb0d-255a-4435-89e6-b311c486daa8' | System | 14 Sep 2020 03:17:20 |
| User entered 'No interference with activity (1)' | System | 14 Sep 2020 03:17:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-13T22:17:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '12c9fb0d-255a-4435-89e6-b311c486daa8' User entered '13 Sep 2020 22:17' | System | 14 Sep 2020 03:17:20 |
| | System | 14 Sep 2020 03:17:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Sep 2020 12:00' | System | 11 Sep 2020 19:02:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Sep 2020 11:59' | System | 11 Sep 2020 19:02:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 12 Sep 2020 17:23:59 |
| User entered 'Day 12' | System | 12 Sep 2020 17:23:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-14T14:31:03', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '519355fa-0491-43ff-accb-72f5162c04ad' User entered 'No interference with activity (1)' | System | 14 Sep 2020 19:31:10 |
| | System | 14 Sep 2020 19:31:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-14T14:31:07', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '519355fa-0491-43ff-accb-72f5162c04ad' User entered '14 Sep 2020 14:31' | System | 14 Sep 2020 19:31:10 |
| | System | 14 Sep 2020 19:31:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Sep 2020 12:00' | System | 12 Sep 2020 17:23:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Sep 2020 11:59' | System | 12 Sep 2020 17:23:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 14 Sep 2020 03:17:20 |
| User entered 'Day 13' | System | 14 Sep 2020 03:17:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-15T12:02:18', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f1063570-5f3e-4429-9b09-0583d1504185' | System | 15 Sep 2020 17:03:37 |
| User entered 'Some interference with activity (2)' | System | 15 Sep 2020 17:03:37 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-15T12:02:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f1063570-5f3e-4429-9b09-0583d1504185' User entered '15 Sep 2020 12:02' | System | 15 Sep 2020 17:03:37 |
| | System | 15 Sep 2020 17:03:37 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Sep 2020 12:00' | System | 14 Sep 2020 03:17:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Sep 2020 11:59' | System | 14 Sep 2020 03:17:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 14 Sep 2020 19:31:10 |
| User entered 'Day 14' | System | 14 Sep 2020 19:31:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-16T12:22:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'd24b62c8-5322-42bd-9b10-440656bbbb86' | System | 16 Sep 2020 17:22:38 |
| User entered 'No interference with activity (1)' | System | 16 Sep 2020 17:22:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-16T12:22:36', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'd24b62c8-5322-42bd-9b10-440656bbbb86' User entered '16 Sep 2020 12:22' | System | 16 Sep 2020 17:22:38 |
| | System | 16 Sep 2020 17:22:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Sep 2020 12:00' | System | 14 Sep 2020 19:31:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Sep 2020 11:59' | System | 14 Sep 2020 19:31:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 15 Sep 2020 17:03:37 |
| User entered 'Day 15' | System | 15 Sep 2020 17:03:37 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-17T12:04:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '61fe8259-8e7d-4593-afb2-52faa5921c6f' User entered 'No interference with activity (1)' | System | 17 Sep 2020 17:05:10 |
| | System | 17 Sep 2020 17:05:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-17T12:04:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '61fe8259-8e7d-4593-afb2-52faa5921c6f' User entered '17 Sep 2020 12:04' | System | 17 Sep 2020 17:05:10 |
| | System | 17 Sep 2020 17:05:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 17:03:37 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 17:03:37 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 16 Sep 2020 17:22:38 |
| User entered 'Day 16' | System | 16 Sep 2020 17:22:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-18T12:12:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'aa9dc46d-6835-4c21-850a-462345a20563' | System | 18 Sep 2020 17:12:18 |
| User entered 'No interference with activity (1)' | System | 18 Sep 2020 17:12:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-18T12:12:15', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'aa9dc46d-6835-4c21-850a-462345a20563' User entered '18 Sep 2020 12:12' | System | 18 Sep 2020 17:12:18 |
| | System | 18 Sep 2020 17:12:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 17:22:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 17:22:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 17 Sep 2020 17:05:10 |
| User entered 'Day 17' | System | 17 Sep 2020 17:05:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-19T14:27:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'd9339d03-ce9c-482f-ae56-c41a2158b9ec' User entered 'No interference with activity (1)' | System | 19 Sep 2020 19:28:03 |
| | System | 19 Sep 2020 19:28:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-19T14:27:59', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'd9339d03-ce9c-482f-ae56-c41a2158b9ec' User entered '19 Sep 2020 14:27' | System | 19 Sep 2020 19:28:03 |
| | System | 19 Sep 2020 19:28:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 17:05:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 17:05:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 18 Sep 2020 17:12:18 |
| User entered 'Day 18' | System | 18 Sep 2020 17:12:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-20T12:16:18', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5a89661a-89c9-4808-9692-de236392c56c' User entered 'No interference with activity (1)' | System | 20 Sep 2020 17:16:25 |
| | System | 20 Sep 2020 17:16:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-20T12:16:24', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5a89661a-89c9-4808-9692-de236392c56c' User entered '20 Sep 2020 12:16' | System | 20 Sep 2020 17:16:25 |
| | System | 20 Sep 2020 17:16:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Sep 2020 12:00' | System | 18 Sep 2020 17:12:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Sep 2020 11:59' | System | 18 Sep 2020 17:12:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 19 Sep 2020 19:28:03 |
| User entered 'Day 19' | System | 19 Sep 2020 19:28:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-21T12:02:08', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2efc6de5-558f-4634-b54b-4b7c29aba3ae' | System | 21 Sep 2020 17:05:19 |
| User entered 'No interference with activity (1)' | System | 21 Sep 2020 17:05:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-21T12:02:11', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2efc6de5-558f-4634-b54b-4b7c29aba3ae' User entered '21 Sep 2020 12:02' | System | 21 Sep 2020 17:05:19 |
| | System | 21 Sep 2020 17:05:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Sep 2020 12:00' | System | 19 Sep 2020 19:28:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Sep 2020 11:59' | System | 19 Sep 2020 19:28:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 20 Sep 2020 17:16:25 |
| User entered 'Day 20' | System | 20 Sep 2020 17:16:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-22T12:00:50', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f6af3aa3-9847-4536-a8d2-1989b9d349f0' | System | 22 Sep 2020 17:01:39 |
| User entered 'No interference with activity (1)' | System | 22 Sep 2020 17:01:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-22T12:00:54', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f6af3aa3-9847-4536-a8d2-1989b9d349f0' User entered '22 Sep 2020 12:00' | System | 22 Sep 2020 17:01:39 |
| | System | 22 Sep 2020 17:01:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Sep 2020 12:00' | System | 20 Sep 2020 17:16:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Sep 2020 11:59' | System | 20 Sep 2020 17:16:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 21 Sep 2020 17:05:19 |
| User entered 'Day 21' | System | 21 Sep 2020 17:05:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-23T12:30:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f0bc15b1-66f6-4e52-9415-5c057273c8ee' User entered 'No interference with activity (1)' | System | 23 Sep 2020 17:30:39 |
| | System | 23 Sep 2020 17:30:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-23T12:30:36', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f0bc15b1-66f6-4e52-9415-5c057273c8ee' User entered '23 Sep 2020 12:30' | System | 23 Sep 2020 17:30:39 |
| | System | 23 Sep 2020 17:30:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 17:05:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 17:05:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 22 Sep 2020 17:01:39 |
| User entered 'Day 22' | System | 22 Sep 2020 17:01:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-24T13:25:36', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e638bd4b-5974-424b-8e95-33af36361bc6' | System | 24 Sep 2020 18:25:40 |
| User entered 'No interference with activity (1)' | System | 24 Sep 2020 18:25:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-24T13:25:38', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e638bd4b-5974-424b-8e95-33af36361bc6' User entered '24 Sep 2020 13:25' | System | 24 Sep 2020 18:25:40 |
| | System | 24 Sep 2020 18:25:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Sep 2020 12:00' | System | 22 Sep 2020 17:01:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '25 Sep 2020 11:59' | System | 22 Sep 2020 17:01:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 23 Sep 2020 17:30:39 |
| User entered 'Day 23' | System | 23 Sep 2020 17:30:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-25T12:07:05', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c08b7e8-c6a6-4de0-b0a8-2e5677b1971b' | System | 25 Sep 2020 17:07:11 |
| User entered 'No interference with activity (1)' | System | 25 Sep 2020 17:07:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-25T12:07:08', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7c08b7e8-c6a6-4de0-b0a8-2e5677b1971b' User entered '25 Sep 2020 12:07' | System | 25 Sep 2020 17:07:11 |
| | System | 25 Sep 2020 17:07:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '25 Sep 2020 12:00' | System | 23 Sep 2020 17:30:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '26 Sep 2020 11:59' | System | 23 Sep 2020 17:30:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 24 Sep 2020 18:25:40 |
| User entered 'Day 24' | System | 24 Sep 2020 18:25:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-26T14:17:11', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6b9ecb76-6896-4a42-9d65-b70deccb89c0' | System | 26 Sep 2020 19:17:15 |
| User entered 'No interference with activity (1)' | System | 26 Sep 2020 19:17:15 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-26T14:17:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6b9ecb76-6896-4a42-9d65-b70deccb89c0' User entered '26 Sep 2020 14:17' | System | 26 Sep 2020 19:17:15 |
| | System | 26 Sep 2020 19:17:15 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '26 Sep 2020 12:00' | System | 24 Sep 2020 18:25:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '27 Sep 2020 11:59' | System | 24 Sep 2020 18:25:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 25 Sep 2020 17:07:11 |
| User entered 'Day 25' | System | 25 Sep 2020 17:07:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-27T12:04:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bb74213c-695a-488f-b24d-481f84aff29f' User entered 'No interference with activity (1)' | System | 27 Sep 2020 17:04:20 |
| | System | 27 Sep 2020 17:04:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-27T12:04:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bb74213c-695a-488f-b24d-481f84aff29f' User entered '27 Sep 2020 12:04' | System | 27 Sep 2020 17:04:20 |
| | System | 27 Sep 2020 17:04:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '27 Sep 2020 12:00' | System | 25 Sep 2020 17:07:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '28 Sep 2020 11:59' | System | 25 Sep 2020 17:07:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 26 Sep 2020 19:17:15 |
| User entered 'Day 26' | System | 26 Sep 2020 19:17:15 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-28T12:28:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8d1badc0-7873-4503-b816-d743da46be79' | System | 28 Sep 2020 17:28:28 |
| User entered 'No interference with activity (1)' | System | 28 Sep 2020 17:28:28 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-28T12:28:24', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8d1badc0-7873-4503-b816-d743da46be79' User entered '28 Sep 2020 12:28' | System | 28 Sep 2020 17:28:28 |
| | System | 28 Sep 2020 17:28:28 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '28 Sep 2020 12:00' | System | 26 Sep 2020 19:17:15 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '29 Sep 2020 11:59' | System | 26 Sep 2020 19:17:15 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 27 Sep 2020 17:04:20 |
| User entered 'Day 27' | System | 27 Sep 2020 17:04:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-29T13:42:53', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6b526d75-434a-4260-a7c1-c2f2bfb8ec38' | System | 29 Sep 2020 18:43:00 |
| User entered 'No interference with activity (1)' | System | 29 Sep 2020 18:43:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-29T13:42:55', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6b526d75-434a-4260-a7c1-c2f2bfb8ec38' User entered '29 Sep 2020 13:42' | System | 29 Sep 2020 18:43:00 |
| | System | 29 Sep 2020 18:43:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '29 Sep 2020 12:00' | System | 27 Sep 2020 17:04:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '30 Sep 2020 11:59' | System | 27 Sep 2020 17:04:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 28 Sep 2020 17:28:28 |
| User entered 'Day 28' | System | 28 Sep 2020 17:28:28 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-30T13:13:05', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e2113f19-8190-499b-9c09-4e12686a0b78' | System | 30 Sep 2020 18:13:11 |
| User entered 'No interference with activity (1)' | System | 30 Sep 2020 18:13:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-30T13:13:08', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e2113f19-8190-499b-9c09-4e12686a0b78' User entered '30 Sep 2020 13:13' | System | 30 Sep 2020 18:13:11 |
| | System | 30 Sep 2020 18:13:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 17:28:28 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 17:28:28 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 29 Sep 2020 18:43:00 |
| User entered 'Day 29' | System | 29 Sep 2020 18:43:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-01T12:00:50', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '43f1b700-72fa-44ea-b0e7-bb7b28c37994' | System | 01 Oct 2020 17:01:13 |
| User entered 'No interference with activity (1)' | System | 01 Oct 2020 17:01:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-01T12:00:53', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '43f1b700-72fa-44ea-b0e7-bb7b28c37994' User entered '01 Oct 2020 12:00' | System | 01 Oct 2020 17:01:13 |
| | System | 01 Oct 2020 17:01:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '01 Oct 2020 12:00' | System | 29 Sep 2020 18:43:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '02 Oct 2020 11:59' | System | 29 Sep 2020 18:43:00 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 30 Sep 2020 18:13:11 |
| User entered 'Day 30' | System | 30 Sep 2020 18:13:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-02T12:22:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6a2b5a1a-91e5-45b5-9648-ce7e77580a39' | System | 02 Oct 2020 17:23:09 |
| User entered 'No interference with activity (1)' | System | 02 Oct 2020 17:23:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-02T12:23:02', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6a2b5a1a-91e5-45b5-9648-ce7e77580a39' User entered '02 Oct 2020 12:23' | System | 02 Oct 2020 17:23:09 |
| | System | 02 Oct 2020 17:23:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '02 Oct 2020 12:00' | System | 30 Sep 2020 18:13:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Oct 2020 11:59' | System | 30 Sep 2020 18:13:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 01 Oct 2020 17:01:13 |
| User entered 'Day 31' | System | 01 Oct 2020 17:01:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-03T12:47:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bd722d94-c278-48db-a060-7da98dbeaa2e' | System | 03 Oct 2020 17:47:49 |
| User entered 'No interference with activity (1)' | System | 03 Oct 2020 17:47:49 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-03T12:47:46', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bd722d94-c278-48db-a060-7da98dbeaa2e' User entered '03 Oct 2020 12:47' | System | 03 Oct 2020 17:47:49 |
| | System | 03 Oct 2020 17:47:49 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Oct 2020 12:00' | System | 01 Oct 2020 17:01:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Oct 2020 11:59' | System | 01 Oct 2020 17:01:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 02 Oct 2020 17:23:09 |
| User entered 'Day 32' | System | 02 Oct 2020 17:23:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-04T13:14:36', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a225d50b-3fc2-4f33-9870-b6525ca6dde2' | System | 04 Oct 2020 18:14:41 |
| User entered 'No interference with activity (1)' | System | 04 Oct 2020 18:14:41 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-04T13:14:39', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a225d50b-3fc2-4f33-9870-b6525ca6dde2' User entered '04 Oct 2020 13:14' | System | 04 Oct 2020 18:14:41 |
| | System | 04 Oct 2020 18:14:41 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Oct 2020 12:00' | System | 02 Oct 2020 17:23:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Oct 2020 11:59' | System | 02 Oct 2020 17:23:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Oct 2020 17:47:49 |
| User entered 'Day 33' | System | 03 Oct 2020 17:47:49 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-05T12:00:32', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'db1ea27e-26ee-4c1b-8bf4-75b9b3552e5e' | System | 05 Oct 2020 17:00:38 |
| User entered 'No interference with activity (1)' | System | 05 Oct 2020 17:00:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-05T12:00:34', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'db1ea27e-26ee-4c1b-8bf4-75b9b3552e5e' User entered '05 Oct 2020 12:00' | System | 05 Oct 2020 17:00:38 |
| | System | 05 Oct 2020 17:00:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Oct 2020 12:00' | System | 03 Oct 2020 17:47:49 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Oct 2020 11:59' | System | 03 Oct 2020 17:47:49 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 04 Oct 2020 18:14:41 |
| User entered 'Day 34' | System | 04 Oct 2020 18:14:41 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-06T12:22:54', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '1960fd15-7fcd-44e5-bc24-18bfbcf848cc' User entered 'No interference with activity (1)' | System | 06 Oct 2020 17:22:59 |
| | System | 06 Oct 2020 17:22:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-06T12:22:56', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '1960fd15-7fcd-44e5-bc24-18bfbcf848cc' User entered '06 Oct 2020 12:22' | System | 06 Oct 2020 17:22:59 |
| | System | 06 Oct 2020 17:22:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Oct 2020 12:00' | System | 04 Oct 2020 18:14:41 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Oct 2020 11:59' | System | 04 Oct 2020 18:14:41 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 05 Oct 2020 17:00:38 |
| User entered 'Day 35' | System | 05 Oct 2020 17:00:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-07T12:00:34', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '09a70f57-59a2-44c4-8e94-95d4e36abc7f' | System | 07 Oct 2020 17:00:48 |
| User entered 'No interference with activity (1)' | System | 07 Oct 2020 17:00:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-07T12:00:37', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '09a70f57-59a2-44c4-8e94-95d4e36abc7f' User entered '07 Oct 2020 12:00' | System | 07 Oct 2020 17:00:48 |
| | System | 07 Oct 2020 17:00:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Oct 2020 12:00' | System | 05 Oct 2020 17:00:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Oct 2020 11:59' | System | 05 Oct 2020 17:00:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 06 Oct 2020 17:22:59 |
| User entered 'Day 36' | System | 06 Oct 2020 17:22:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-08T14:01:24', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '56f920d4-2e57-4277-ae7f-530753a4b58a' | System | 08 Oct 2020 19:01:34 |
| User entered 'No interference with activity (1)' | System | 08 Oct 2020 19:01:34 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-08T14:01:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '56f920d4-2e57-4277-ae7f-530753a4b58a' User entered '08 Oct 2020 14:01' | System | 08 Oct 2020 19:01:34 |
| | System | 08 Oct 2020 19:01:34 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Oct 2020 12:00' | System | 06 Oct 2020 17:22:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Oct 2020 11:59' | System | 06 Oct 2020 17:22:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Oct 2020 17:00:48 |
| User entered 'Day 37' | System | 07 Oct 2020 17:00:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-09T12:00:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6fbd668b-0325-4f35-8c1e-915358030ea1' | System | 09 Oct 2020 17:00:40 |
| User entered 'No interference with activity (1)' | System | 09 Oct 2020 17:00:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-09T12:00:35', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6fbd668b-0325-4f35-8c1e-915358030ea1' User entered '09 Oct 2020 12:00' | System | 09 Oct 2020 17:00:40 |
| | System | 09 Oct 2020 17:00:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Oct 2020 12:00' | System | 07 Oct 2020 17:00:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Oct 2020 11:59' | System | 07 Oct 2020 17:00:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 08 Oct 2020 19:01:34 |
| User entered 'Day 38' | System | 08 Oct 2020 19:01:34 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-10T12:20:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '519de639-f252-43c8-88c6-fb0f25d88665' | System | 10 Oct 2020 17:20:19 |
| User entered 'No interference with activity (1)' | System | 10 Oct 2020 17:20:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-10T12:20:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '519de639-f252-43c8-88c6-fb0f25d88665' User entered '10 Oct 2020 12:20' | System | 10 Oct 2020 17:20:19 |
| | System | 10 Oct 2020 17:20:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Oct 2020 12:00' | System | 08 Oct 2020 19:01:34 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Oct 2020 11:59' | System | 08 Oct 2020 19:01:34 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 09 Oct 2020 17:00:40 |
| User entered 'Day 39' | System | 09 Oct 2020 17:00:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-11T15:35:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a9ad44b2-e220-4046-9544-f88a4555fe15' | System | 11 Oct 2020 20:35:25 |
| User entered 'No interference with activity (1)' | System | 11 Oct 2020 20:35:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-11T15:35:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a9ad44b2-e220-4046-9544-f88a4555fe15' | System | 11 Oct 2020 20:35:25 |
| User entered '11 Oct 2020 15:35' | System | 11 Oct 2020 20:35:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Oct 2020 12:00' | System | 09 Oct 2020 17:00:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Oct 2020 11:59' | System | 09 Oct 2020 17:00:40 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 10 Oct 2020 17:20:19 |
| User entered 'Day 40' | System | 10 Oct 2020 17:20:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-12T12:01:09', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8cf6777b-546a-40f1-aa52-1d4045dfb961' | System | 12 Oct 2020 17:02:09 |
| User entered 'No interference with activity (1)' | System | 12 Oct 2020 17:02:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-12T12:01:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8cf6777b-546a-40f1-aa52-1d4045dfb961' User entered '12 Oct 2020 12:01' | System | 12 Oct 2020 17:02:09 |
| | System | 12 Oct 2020 17:02:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Oct 2020 12:00' | System | 10 Oct 2020 17:20:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Oct 2020 11:59' | System | 10 Oct 2020 17:20:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 11 Oct 2020 20:35:25 |
| User entered 'Day 41' | System | 11 Oct 2020 20:35:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-13T12:01:55', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '550799a0-e95a-488b-ba3b-edc962d2f6f0' | System | 13 Oct 2020 17:02:08 |
| User entered 'No interference with activity (1)' | System | 13 Oct 2020 17:02:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-13T12:01:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '550799a0-e95a-488b-ba3b-edc962d2f6f0' User entered '13 Oct 2020 12:01' | System | 13 Oct 2020 17:02:08 |
| | System | 13 Oct 2020 17:02:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Oct 2020 12:00' | System | 11 Oct 2020 20:35:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Oct 2020 11:59' | System | 11 Oct 2020 20:35:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 12 Oct 2020 17:02:09 |
| User entered 'Day 42' | System | 12 Oct 2020 17:02:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T14:40:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c4616ce6-b28c-4266-89c4-299c008a6320' | System | 14 Oct 2020 19:40:55 |
| User entered 'Some interference with activity (2)' | System | 14 Oct 2020 19:40:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T14:40:51', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'c4616ce6-b28c-4266-89c4-299c008a6320' User entered '14 Oct 2020 14:40' | System | 14 Oct 2020 19:40:55 |
| | System | 14 Oct 2020 19:40:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Oct 2020 12:00' | System | 12 Oct 2020 17:02:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Oct 2020 11:59' | System | 12 Oct 2020 17:02:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 13 Oct 2020 17:02:08 |
| User entered 'Day 43' | System | 13 Oct 2020 17:02:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-15T12:01:32', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'fa956a11-50ef-4e8b-b745-66d969937956' | System | 15 Oct 2020 17:01:58 |
| User entered 'Some interference with activity (2)' | System | 15 Oct 2020 17:01:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-15T12:01:35', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'fa956a11-50ef-4e8b-b745-66d969937956' User entered '15 Oct 2020 12:01' | System | 15 Oct 2020 17:01:58 |
| | System | 15 Oct 2020 17:01:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Oct 2020 12:00' | System | 13 Oct 2020 17:02:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Oct 2020 11:59' | System | 13 Oct 2020 17:02:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 14 Oct 2020 19:40:55 |
| User entered 'Day 44' | System | 14 Oct 2020 19:40:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-16T13:16:35', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '3e95a51e-2727-4965-a47b-0437574f3792' | System | 16 Oct 2020 18:16:42 |
| User entered 'No interference with activity (1)' | System | 16 Oct 2020 18:16:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-16T13:16:39', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '3e95a51e-2727-4965-a47b-0437574f3792' | System | 16 Oct 2020 18:16:42 |
| User entered '16 Oct 2020 13:16' | System | 16 Oct 2020 18:16:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Oct 2020 12:00' | System | 14 Oct 2020 19:40:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Oct 2020 11:59' | System | 14 Oct 2020 19:40:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 15 Oct 2020 17:01:58 |
| User entered 'Day 45' | System | 15 Oct 2020 17:01:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-17T12:01:06', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b4cfe9ff-6481-46fe-a669-97ec136f78e4' | System | 17 Oct 2020 17:01:19 |
| User entered 'No interference with activity (1)' | System | 17 Oct 2020 17:01:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-17T12:01:10', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b4cfe9ff-6481-46fe-a669-97ec136f78e4' User entered '17 Oct 2020 12:01' | System | 17 Oct 2020 17:01:19 |
| | System | 17 Oct 2020 17:01:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Oct 2020 12:00' | System | 15 Oct 2020 17:01:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Oct 2020 11:59' | System | 15 Oct 2020 17:01:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 16 Oct 2020 18:16:42 |
| User entered 'Day 46' | System | 16 Oct 2020 18:16:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-18T12:28:29', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '09aaccfc-39c3-473a-9b27-a5d4df628965' | System | 18 Oct 2020 17:28:52 |
| User entered 'No interference with activity (1)' | System | 18 Oct 2020 17:28:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-18T12:28:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '09aaccfc-39c3-473a-9b27-a5d4df628965' User entered '18 Oct 2020 12:28' | System | 18 Oct 2020 17:28:52 |
| | System | 18 Oct 2020 17:28:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Oct 2020 12:00' | System | 16 Oct 2020 18:16:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Oct 2020 11:59' | System | 16 Oct 2020 18:16:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 17 Oct 2020 17:01:19 |
| User entered 'Day 47' | System | 17 Oct 2020 17:01:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-19T12:46:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4ae69ad7-2eb9-4a7d-a128-cee272e0c515' | System | 19 Oct 2020 17:52:54 |
| User entered 'No interference with activity (1)' | System | 19 Oct 2020 17:52:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-19T12:46:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4ae69ad7-2eb9-4a7d-a128-cee272e0c515' User entered '19 Oct 2020 12:46' | System | 19 Oct 2020 17:52:54 |
| | System | 19 Oct 2020 17:52:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Oct 2020 12:00' | System | 17 Oct 2020 17:01:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Oct 2020 11:59' | System | 17 Oct 2020 17:01:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 18 Oct 2020 17:28:52 |
| User entered 'Day 48' | System | 18 Oct 2020 17:28:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-21T08:50:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '3fc5760e-66e2-42df-9c0f-4b83dca0cfd0' | System | 21 Oct 2020 13:50:19 |
| User entered 'Some interference with activity (2)' | System | 21 Oct 2020 13:50:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-21T08:50:14', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '3fc5760e-66e2-42df-9c0f-4b83dca0cfd0' | System | 21 Oct 2020 13:50:19 |
| User entered '21 Oct 2020 08:50' | System | 21 Oct 2020 13:50:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Oct 2020 12:00' | System | 18 Oct 2020 17:28:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Oct 2020 11:59' | System | 18 Oct 2020 17:28:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 19 Oct 2020 17:52:54 |
| User entered 'Day 49' | System | 19 Oct 2020 17:52:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T09:03:02', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2ec26bac-499d-42ee-befc-143bf3e15214' | System | 22 Oct 2020 14:03:09 |
| User entered 'No interference with activity (1)' | System | 22 Oct 2020 14:03:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T09:03:05', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2ec26bac-499d-42ee-befc-143bf3e15214' User entered '22 Oct 2020 09:03' | System | 22 Oct 2020 14:03:09 |
| | System | 22 Oct 2020 14:03:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Oct 2020 12:00' | System | 19 Oct 2020 17:52:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Oct 2020 11:59' | System | 19 Oct 2020 17:52:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 21 Oct 2020 13:50:19 |
| User entered 'Day 50' | System | 21 Oct 2020 13:50:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T12:48:38', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ba410d1b-ab5c-4a50-a0a5-2fe269fff18a' User entered 'No interference with activity (1)' | System | 22 Oct 2020 17:48:45 |
| | System | 22 Oct 2020 17:48:45 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T12:48:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ba410d1b-ab5c-4a50-a0a5-2fe269fff18a' User entered '22 Oct 2020 12:48' | System | 22 Oct 2020 17:48:45 |
| | System | 22 Oct 2020 17:48:45 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Oct 2020 12:00' | System | 21 Oct 2020 13:50:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Oct 2020 11:59' | System | 21 Oct 2020 13:50:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 22 Oct 2020 14:03:09 |
| User entered 'Day 51' | System | 22 Oct 2020 14:03:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| | | |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Oct 2020 12:00' | System | 22 Oct 2020 14:03:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Oct 2020 11:59' | System | 22 Oct 2020 14:03:09 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 22 Oct 2020 17:48:45 |
| User entered 'Day 52' | System | 22 Oct 2020 17:48:45 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Oct 2020 12:00' | System | 22 Oct 2020 17:48:45 |

US3452332

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '25 Oct 2020 11:59' | System | 22 Oct 2020 17:48:45 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 08 Sep 2020 17:05:13 |
| User entered 'Day 8' | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-10T12:01:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '688b1798-2533-47e0-b8b6-b717e95ae800' User entered 'No (N)' | System | 10 Sep 2020 17:02:31 |
| | System | 10 Sep 2020 17:02:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-10T12:01:57', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '688b1798-2533-47e0-b8b6-b717e95ae800' User entered '10 Sep 2020 12:01' | System | 10 Sep 2020 17:02:31 |
| | System | 10 Sep 2020 17:02:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 09 Sep 2020 17:05:02 |
| User entered 'Day 9' | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-11T14:02:45', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8bf5890f-b602-4afa-82b4-6466d98a9d39' User entered 'No (N)' | System | 11 Sep 2020 19:02:51 |
| | System | 11 Sep 2020 19:02:51 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-11T14:02:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8bf5890f-b602-4afa-82b4-6466d98a9d39' User entered '11 Sep 2020 14:02' | System | 11 Sep 2020 19:02:51 |
| | System | 11 Sep 2020 19:02:51 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Sep 2020 12:00' | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Sep 2020 11:59' | System | 09 Sep 2020 17:05:02 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 10 Sep 2020 17:01:20 |
| User entered 'Day 10' | System | 10 Sep 2020 17:01:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-12T12:24:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b37e4eae-b899-431c-a9cd-9845a1ed69c7' User entered 'No (N)' | System | 12 Sep 2020 17:24:07 |
| | System | 12 Sep 2020 17:24:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-12T12:24:05', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'b37e4eae-b899-431c-a9cd-9845a1ed69c7' User entered '12 Sep 2020 12:24' | System | 12 Sep 2020 17:24:07 |
| | System | 12 Sep 2020 17:24:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Sep 2020 12:00' | System | 10 Sep 2020 17:01:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Sep 2020 11:59' | System | 10 Sep 2020 17:01:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 11 Sep 2020 19:02:29 |
| User entered 'Day 11' | System | 11 Sep 2020 19:02:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-13T22:17:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'cb906afa-3d8e-428a-a506-1faf6a9a0eb7' User entered 'No (N)' | System | 14 Sep 2020 03:17:26 |
| | System | 14 Sep 2020 03:17:26 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-13T22:17:25', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'cb906afa-3d8e-428a-a506-1faf6a9a0eb7' | System | 14 Sep 2020 03:17:26 |
| User entered '13 Sep 2020 22:17' | System | 14 Sep 2020 03:17:26 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Sep 2020 12:00' | System | 11 Sep 2020 19:02:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Sep 2020 11:59' | System | 11 Sep 2020 19:02:29 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 12 Sep 2020 17:23:52 |
| User entered 'Day 12' | System | 12 Sep 2020 17:23:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-14T14:31:11', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e309e81e-60db-468c-bb48-20b886f150b3' User entered 'No (N)' | System | 14 Sep 2020 19:31:17 |
| | System | 14 Sep 2020 19:31:17 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-14T14:31:14', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e309e81e-60db-468c-bb48-20b886f150b3' User entered '14 Sep 2020 14:31' | System | 14 Sep 2020 19:31:17 |
| | System | 14 Sep 2020 19:31:17 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Sep 2020 12:00' | System | 12 Sep 2020 17:23:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Sep 2020 11:59' | System | 12 Sep 2020 17:23:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 14 Sep 2020 03:17:10 |
| User entered 'Day 13' | System | 14 Sep 2020 03:17:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-15T12:02:29', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '754cae2b-331b-4bb2-8243-457a62178920' User entered 'Yes (Y)' | System | 15 Sep 2020 17:03:46 |
| | System | 15 Sep 2020 17:03:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-15T12:02:36', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '754cae2b-331b-4bb2-8243-457a62178920' User entered '15 Sep 2020 12:02' | System | 15 Sep 2020 17:03:46 |
| | System | 15 Sep 2020 17:03:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Sep 2020 12:00' | System | 14 Sep 2020 03:17:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Sep 2020 11:59' | System | 14 Sep 2020 03:17:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 14 Sep 2020 19:31:04 |
| User entered 'Day 14' | System | 14 Sep 2020 19:31:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-16T12:22:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8ecf6e67-7e4b-4d5c-ab44-a03b800c801e' User entered 'Yes (Y)' | System | 16 Sep 2020 17:22:55 |
| | System | 16 Sep 2020 17:22:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-16T12:22:51', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8ecf6e67-7e4b-4d5c-ab44-a03b800c801e' User entered '16 Sep 2020 12:22' | System | 16 Sep 2020 17:22:55 |
| | System | 16 Sep 2020 17:22:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Sep 2020 12:00' | System | 14 Sep 2020 19:31:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Sep 2020 11:59' | System | 14 Sep 2020 19:31:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 15 Sep 2020 17:03:25 |
| User entered 'Day 15' | System | 15 Sep 2020 17:03:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-17T12:04:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bb6d05f5-f807-42b0-9712-1a107a0bcc01' User entered 'No (N)' | System | 17 Sep 2020 17:05:12 |
| | System | 17 Sep 2020 17:05:12 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-17T12:04:26', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bb6d05f5-f807-42b0-9712-1a107a0bcc01' User entered '17 Sep 2020 12:04' | System | 17 Sep 2020 17:05:12 |
| | System | 17 Sep 2020 17:05:12 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 17:03:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 17:03:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 16 Sep 2020 17:22:23 |
| User entered 'Day 16' | System | 16 Sep 2020 17:22:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-18T12:12:22', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '888f87cb-b95d-4394-9a9b-f4bb0b56a040' User entered 'No (N)' | System | 18 Sep 2020 17:12:27 |
| | System | 18 Sep 2020 17:12:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-18T12:12:24', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '888f87cb-b95d-4394-9a9b-f4bb0b56a040' User entered '18 Sep 2020 12:12' | System | 18 Sep 2020 17:12:27 |
| | System | 18 Sep 2020 17:12:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 17:22:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 17:22:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 17 Sep 2020 17:05:05 |
| User entered 'Day 17' | System | 17 Sep 2020 17:05:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-19T14:28:08', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ec4cebd4-5220-4e7f-8521-c57280e4b78d' User entered 'No (N)' | System | 19 Sep 2020 19:28:16 |
| | System | 19 Sep 2020 19:28:16 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-19T14:28:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ec4cebd4-5220-4e7f-8521-c57280e4b78d' User entered '19 Sep 2020 14:28' | System | 19 Sep 2020 19:28:16 |
| | System | 19 Sep 2020 19:28:16 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 17:05:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 17:05:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 18 Sep 2020 17:12:14 |
| User entered 'Day 18' | System | 18 Sep 2020 17:12:14 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-20T12:16:30', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '91b68917-9913-494f-b445-57132782ed9a' User entered 'No (N)' | System | 20 Sep 2020 17:16:36 |
| | System | 20 Sep 2020 17:16:36 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-20T12:16:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '91b68917-9913-494f-b445-57132782ed9a' User entered '20 Sep 2020 12:16' | System | 20 Sep 2020 17:16:36 |
| | System | 20 Sep 2020 17:16:36 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Sep 2020 12:00' | System | 18 Sep 2020 17:12:14 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Sep 2020 11:59' | System | 18 Sep 2020 17:12:14 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 19 Sep 2020 19:27:46 |
| User entered 'Day 19' | System | 19 Sep 2020 19:27:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-21T12:02:15', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '51ce52fc-1579-4780-a634-edde3bfab747' User entered 'No (N)' | System | 21 Sep 2020 17:05:22 |
| | System | 21 Sep 2020 17:05:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-21T12:02:18', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '51ce52fc-1579-4780-a634-edde3bfab747' User entered '21 Sep 2020 12:02' | System | 21 Sep 2020 17:05:22 |
| | System | 21 Sep 2020 17:05:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Sep 2020 12:00' | System | 19 Sep 2020 19:27:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Sep 2020 11:59' | System | 19 Sep 2020 19:27:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 20 Sep 2020 17:16:16 |
| User entered 'Day 20' | System | 20 Sep 2020 17:16:16 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-22T12:01:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4f1b1724-73ba-4a2d-9e43-a4e43f5fa075' User entered 'No (N)' | System | 22 Sep 2020 17:01:50 |
| | System | 22 Sep 2020 17:01:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-22T12:01:03', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4f1b1724-73ba-4a2d-9e43-a4e43f5fa075' User entered '22 Sep 2020 12:01' | System | 22 Sep 2020 17:01:50 |
| | System | 22 Sep 2020 17:01:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Sep 2020 12:00' | System | 20 Sep 2020 17:16:16 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Sep 2020 11:59' | System | 20 Sep 2020 17:16:16 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 21 Sep 2020 17:05:13 |
| User entered 'Day 21' | System | 21 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-23T12:30:41', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6fd04fb8-a125-44d2-ac71-50b9fe7856ad' User entered 'No (N)' | System | 23 Sep 2020 17:30:46 |
| | System | 23 Sep 2020 17:30:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-23T12:30:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6fd04fb8-a125-44d2-ac71-50b9fe7856ad' User entered '23 Sep 2020 12:30' | System | 23 Sep 2020 17:30:46 |
| | System | 23 Sep 2020 17:30:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 17:05:13 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 22 Sep 2020 17:01:24 |
| User entered 'Day 22' | System | 22 Sep 2020 17:01:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-24T13:25:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '28b58a9f-5830-43e1-9482-22ae3be027' | System | 24 Sep 2020 18:25:47 |
| User entered 'No (N)' | System | 24 Sep 2020 18:25:47 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-24T13:25:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '28b58a9f-5830-43e1-9482-22ae3be027' User entered '24 Sep 2020 13:25' | System | 24 Sep 2020 18:25:47 |
| | System | 24 Sep 2020 18:25:47 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Sep 2020 12:00' | System | 22 Sep 2020 17:01:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '25 Sep 2020 11:59' | System | 22 Sep 2020 17:01:24 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 23 Sep 2020 17:30:32 |
| User entered 'Day 23' | System | 23 Sep 2020 17:30:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-25T12:07:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '13744015-626c-455c-b1e7-be7510f35a90' User entered 'No (N)' | System | 25 Sep 2020 17:07:25 |
| | System | 25 Sep 2020 17:07:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-25T12:07:24', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '13744015-626c-455c-b1e7-be7510f35a90' User entered '25 Sep 2020 12:07' | System | 25 Sep 2020 17:07:25 |
| | System | 25 Sep 2020 17:07:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '25 Sep 2020 12:00' | System | 23 Sep 2020 17:30:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '26 Sep 2020 11:59' | System | 23 Sep 2020 17:30:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 24 Sep 2020 18:25:38 |
| User entered 'Day 24' | System | 24 Sep 2020 18:25:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-26T14:17:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '785affc9-d293-4b3f-a482-f0cb3e98e104' User entered 'No (N)' | System | 26 Sep 2020 19:17:27 |
| | System | 26 Sep 2020 19:17:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-26T14:17:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '785affc9-d293-4b3f-a482-f0cb3e98e104' User entered '26 Sep 2020 14:17' | System | 26 Sep 2020 19:17:27 |
| | System | 26 Sep 2020 19:17:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '26 Sep 2020 12:00' | System | 24 Sep 2020 18:25:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '27 Sep 2020 11:59' | System | 24 Sep 2020 18:25:38 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 25 Sep 2020 17:06:59 |
| User entered 'Day 25' | System | 25 Sep 2020 17:06:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-27T12:04:19', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e2eb9126-e2c8-4059-93b7-334941110778' User entered 'No (N)' | System | 27 Sep 2020 17:04:26 |
| | System | 27 Sep 2020 17:04:26 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-27T12:04:22', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e2eb9126-e2c8-4059-93b7-334941110778' User entered '27 Sep 2020 12:04' | System | 27 Sep 2020 17:04:26 |
| | System | 27 Sep 2020 17:04:26 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '27 Sep 2020 12:00' | System | 25 Sep 2020 17:06:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '28 Sep 2020 11:59' | System | 25 Sep 2020 17:06:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 26 Sep 2020 19:17:08 |
| User entered 'Day 26' | System | 26 Sep 2020 19:17:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-28T12:28:29', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '92fcab59-efba-4c4e-a7b7-4b1b2049952e' User entered 'No (N)' | System | 28 Sep 2020 17:28:36 |
| | System | 28 Sep 2020 17:28:36 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-28T12:28:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '92fcab59-efba-4c4e-a7b7-4b1b2049952e' User entered '28 Sep 2020 12:28' | System | 28 Sep 2020 17:28:36 |
| | System | 28 Sep 2020 17:28:36 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '28 Sep 2020 12:00' | System | 26 Sep 2020 19:17:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '29 Sep 2020 11:59' | System | 26 Sep 2020 19:17:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 27 Sep 2020 17:04:10 |
| User entered 'Day 27' | System | 27 Sep 2020 17:04:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-29T13:43:05', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bb547871-4f09-4844-b89e-7be15b858bf2' | System | 29 Sep 2020 18:43:11 |
| User entered 'No (N)' | System | 29 Sep 2020 18:43:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-29T13:43:07', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'bb547871-4f09-4844-b89e-7be15b858bf2' User entered '29 Sep 2020 13:43' | System | 29 Sep 2020 18:43:11 |
| | System | 29 Sep 2020 18:43:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '29 Sep 2020 12:00' | System | 27 Sep 2020 17:04:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '30 Sep 2020 11:59' | System | 27 Sep 2020 17:04:10 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 28 Sep 2020 17:28:22 |
| User entered 'Day 28' | System | 28 Sep 2020 17:28:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-30T13:13:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'da0b4fa1-2565-47ed-9d1d-446ae748fa0b' User entered 'No (N)' | System | 30 Sep 2020 18:13:22 |
| | System | 30 Sep 2020 18:13:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-09-30T13:13:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'da0b4fa1-2565-47ed-9d1d-446ae748fa0b' User entered '30 Sep 2020 13:13' | System | 30 Sep 2020 18:13:22 |
| | System | 30 Sep 2020 18:13:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 17:28:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 17:28:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 29 Sep 2020 18:42:51 |
| User entered 'Day 29' | System | 29 Sep 2020 18:42:51 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-01T12:00:56', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8df57c4d-61c6-4f8e-a7b3-d3920d448384' User entered 'No (N)' | System | 01 Oct 2020 17:01:25 |
| | System | 01 Oct 2020 17:01:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-01T12:00:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8df57c4d-61c6-4f8e-a7b3-d3920d448384' User entered '01 Oct 2020 12:00' | System | 01 Oct 2020 17:01:25 |
| | System | 01 Oct 2020 17:01:25 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '01 Oct 2020 12:00' | System | 29 Sep 2020 18:42:51 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '02 Oct 2020 11:59' | System | 29 Sep 2020 18:42:51 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 30 Sep 2020 18:13:05 |
| User entered 'Day 30' | System | 30 Sep 2020 18:13:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-02T12:23:06', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5fb7e6b8-bcc1-40e4-9db3-e99510de556c' User entered 'No (N)' | System | 02 Oct 2020 17:23:11 |
| | System | 02 Oct 2020 17:23:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-02T12:23:09', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5fb7e6b8-bcc1-40e4-9db3-e99510de556c' User entered '02 Oct 2020 12:23' | System | 02 Oct 2020 17:23:11 |
| | System | 02 Oct 2020 17:23:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '02 Oct 2020 12:00' | System | 30 Sep 2020 18:13:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Oct 2020 11:59' | System | 30 Sep 2020 18:13:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 01 Oct 2020 17:00:58 |
| User entered 'Day 31' | System | 01 Oct 2020 17:00:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-03T12:47:51', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7eb3e663-6f3b-4efb-9bc3-a389f3edbb90' | System | 03 Oct 2020 17:47:55 |
| User entered 'No (N)' | System | 03 Oct 2020 17:47:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-03T12:47:53', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7eb3e663-6f3b-4efb-9bc3-a389f3edbb90' User entered '03 Oct 2020 12:47' | System | 03 Oct 2020 17:47:55 |
| | System | 03 Oct 2020 17:47:55 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '03 Oct 2020 12:00' | System | 01 Oct 2020 17:00:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Oct 2020 11:59' | System | 01 Oct 2020 17:00:58 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 02 Oct 2020 17:22:57 |
| User entered 'Day 32' | System | 02 Oct 2020 17:22:57 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-04T13:14:43', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0bf501f0-b8ba-4064-a579-b671c0a42da3' User entered 'No (N)' | System | 04 Oct 2020 18:14:48 |
| | System | 04 Oct 2020 18:14:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-04T13:14:45', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0bf501f0-b8ba-4064-a579-b671c0a42da3' User entered '04 Oct 2020 13:14' | System | 04 Oct 2020 18:14:48 |
| | System | 04 Oct 2020 18:14:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '04 Oct 2020 12:00' | System | 02 Oct 2020 17:22:57 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Oct 2020 11:59' | System | 02 Oct 2020 17:22:57 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 03 Oct 2020 17:47:42 |
| User entered 'Day 33' | System | 03 Oct 2020 17:47:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-05T12:00:38', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '95d7d306-4814-44b5-a7ae-18e9a02750e1' User entered 'No (N)' | System | 05 Oct 2020 17:00:46 |
| | System | 05 Oct 2020 17:00:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-05T12:00:40', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '95d7d306-4814-44b5-a7ae-18e9a02750e1' User entered '05 Oct 2020 12:00' | System | 05 Oct 2020 17:00:46 |
| | System | 05 Oct 2020 17:00:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '05 Oct 2020 12:00' | System | 03 Oct 2020 17:47:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Oct 2020 11:59' | System | 03 Oct 2020 17:47:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 04 Oct 2020 18:14:33 |
| User entered 'Day 34' | System | 04 Oct 2020 18:14:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-06T12:22:59', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9b86d098-cf33-4b93-adce-27efdc094334' User entered 'No (N)' | System | 06 Oct 2020 17:23:08 |
| | System | 06 Oct 2020 17:23:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-06T12:23:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9b86d098-cf33-4b93-adce-27efdc094334' User entered '06 Oct 2020 12:23' | System | 06 Oct 2020 17:23:08 |
| | System | 06 Oct 2020 17:23:08 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '06 Oct 2020 12:00' | System | 04 Oct 2020 18:14:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Oct 2020 11:59' | System | 04 Oct 2020 18:14:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 05 Oct 2020 17:00:31 |
| User entered 'Day 35' | System | 05 Oct 2020 17:00:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-07T12:00:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'cbac98fd-9b23-4a3a-97ce-169f9f64fcba' User entered 'No (N)' | System | 07 Oct 2020 17:01:05 |
| | System | 07 Oct 2020 17:01:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-07T12:00:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'cbac98fd-9b23-4a3a-97ce-169f9f64fcba' User entered '07 Oct 2020 12:00' | System | 07 Oct 2020 17:01:05 |
| | System | 07 Oct 2020 17:01:05 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '07 Oct 2020 12:00' | System | 05 Oct 2020 17:00:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Oct 2020 11:59' | System | 05 Oct 2020 17:00:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 06 Oct 2020 17:22:52 |
| User entered 'Day 36' | System | 06 Oct 2020 17:22:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-08T14:01:38', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5843f5e5-5d6f-4e17-abbe-a88e34778af1' User entered 'No (N)' | System | 08 Oct 2020 19:01:49 |
| | System | 08 Oct 2020 19:01:49 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-08T14:01:46', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '5843f5e5-5d6f-4e17-abbe-a88e34778af1' User entered '08 Oct 2020 14:01' | System | 08 Oct 2020 19:01:49 |
| | System | 08 Oct 2020 19:01:49 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '08 Oct 2020 12:00' | System | 06 Oct 2020 17:22:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Oct 2020 11:59' | System | 06 Oct 2020 17:22:52 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Oct 2020 17:00:43 |
| User entered 'Day 37' | System | 07 Oct 2020 17:00:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-09T12:00:39', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'fdc0c7ce-8733-4eec-a790-6d1ef1b4a5e9' User entered 'No (N)' | System | 09 Oct 2020 17:00:46 |
| | System | 09 Oct 2020 17:00:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-09T12:00:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'fdc0c7ce-8733-4eec-a790-6d1ef1b4a5e9' User entered '09 Oct 2020 12:00' | System | 09 Oct 2020 17:00:46 |
| | System | 09 Oct 2020 17:00:46 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '09 Oct 2020 12:00' | System | 07 Oct 2020 17:00:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Oct 2020 11:59' | System | 07 Oct 2020 17:00:43 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 08 Oct 2020 19:01:23 |
| User entered 'Day 38' | System | 08 Oct 2020 19:01:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-10T12:20:25', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8daf01a9-468f-46b2-955d-43cc04e7eb97' | System | 10 Oct 2020 17:20:31 |
| User entered 'No (N)' | System | 10 Oct 2020 17:20:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-10T12:20:28', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8daf01a9-468f-46b2-955d-43cc04e7eb97' | System | 10 Oct 2020 17:20:31 |
| User entered '10 Oct 2020 12:20' | System | 10 Oct 2020 17:20:31 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '10 Oct 2020 12:00' | System | 08 Oct 2020 19:01:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Oct 2020 11:59' | System | 08 Oct 2020 19:01:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 09 Oct 2020 17:00:33 |
| User entered 'Day 39' | System | 09 Oct 2020 17:00:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-11T15:35:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6429ce1e-13b2-40e1-ae86-7025abf5b711' User entered 'No (N)' | System | 11 Oct 2020 20:35:33 |
| | System | 11 Oct 2020 20:35:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-11T15:35:31', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '6429ce1e-13b2-40e1-ae86-7025abf5b711' User entered '11 Oct 2020 15:35' | System | 11 Oct 2020 20:35:33 |
| | System | 11 Oct 2020 20:35:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '11 Oct 2020 12:00' | System | 09 Oct 2020 17:00:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Oct 2020 11:59' | System | 09 Oct 2020 17:00:33 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 10 Oct 2020 17:20:11 |
| User entered 'Day 40' | System | 10 Oct 2020 17:20:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-12T12:01:35', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9987fba2-ee4e-4ca0-9ddc-925448db00ac' User entered 'Yes (Y)' | System | 12 Oct 2020 17:02:19 |
| | System | 12 Oct 2020 17:02:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-12T12:01:38', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9987fba2-ee4e-4ca0-9ddc-925448db00ac' User entered '12 Oct 2020 12:01' | System | 12 Oct 2020 17:02:19 |
| | System | 12 Oct 2020 17:02:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '12 Oct 2020 12:00' | System | 10 Oct 2020 17:20:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Oct 2020 11:59' | System | 10 Oct 2020 17:20:11 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 11 Oct 2020 20:35:18 |
| User entered 'Day 41' | System | 11 Oct 2020 20:35:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-13T12:02:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7ef4742e-d5f1-4daf-b0be-f1e2275b1e63' | System | 13 Oct 2020 17:02:23 |
| User entered 'Yes (Y)' | System | 13 Oct 2020 17:02:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-13T12:02:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '7ef4742e-d5f1-4daf-b0be-f1e2275b1e63' User entered '13 Oct 2020 12:02' | System | 13 Oct 2020 17:02:23 |
| | System | 13 Oct 2020 17:02:23 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '13 Oct 2020 12:00' | System | 11 Oct 2020 20:35:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Oct 2020 11:59' | System | 11 Oct 2020 20:35:18 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 12 Oct 2020 17:02:07 |
| User entered 'Day 42' | System | 12 Oct 2020 17:02:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T14:41:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0d584df2-ca6d-40cd-87dc-28536c785b3b' User entered 'Yes (Y)' | System | 14 Oct 2020 19:42:15 |
| | System | 14 Oct 2020 19:42:15 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T14:42:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '0d584df2-ca6d-40cd-87dc-28536c785b3b' User entered '14 Oct 2020 14:42' | System | 14 Oct 2020 19:42:15 |
| | System | 14 Oct 2020 19:42:15 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '14 Oct 2020 12:00' | System | 12 Oct 2020 17:02:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Oct 2020 11:59' | System | 12 Oct 2020 17:02:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 13 Oct 2020 17:01:48 |
| User entered 'Day 43' | System | 13 Oct 2020 17:01:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-15T12:03:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '82f851ed-2485-4ae5-9e4c-51411c7a57d7' User entered 'Yes (Y)' | System | 15 Oct 2020 17:03:54 |
| | System | 15 Oct 2020 17:03:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-15T12:03:51', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '82f851ed-2485-4ae5-9e4c-51411c7a57d7' User entered '15 Oct 2020 12:03' | System | 15 Oct 2020 17:03:54 |
| | System | 15 Oct 2020 17:03:54 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '15 Oct 2020 12:00' | System | 13 Oct 2020 17:01:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Oct 2020 11:59' | System | 13 Oct 2020 17:01:48 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 14 Oct 2020 19:40:39 |
| User entered 'Day 44' | System | 14 Oct 2020 19:40:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-16T13:16:55', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '112b00e0-fb1b-46ef-8af2-9f9b415c2bc5' User entered 'No (N)' | System | 16 Oct 2020 18:17:01 |
| | System | 16 Oct 2020 18:17:01 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-16T13:16:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '112b00e0-fb1b-46ef-8af2-9f9b415c2bc5' User entered '16 Oct 2020 13:16' | System | 16 Oct 2020 18:17:01 |
| | System | 16 Oct 2020 18:17:01 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '16 Oct 2020 12:00' | System | 14 Oct 2020 19:40:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Oct 2020 11:59' | System | 14 Oct 2020 19:40:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 15 Oct 2020 17:01:42 |
| User entered 'Day 45' | System | 15 Oct 2020 17:01:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-17T12:01:14', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f74b6b1f-4596-4dd0-88b0-8d71aadafe' | System | 17 Oct 2020 17:01:22 |
| User entered 'No (N)' | System | 17 Oct 2020 17:01:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-17T12:01:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'f74b6b1f-4596-4dd0-88b0-8d71aadafe' | System | 17 Oct 2020 17:01:22 |
| User entered '17 Oct 2020 12:01' | System | 17 Oct 2020 17:01:22 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '17 Oct 2020 12:00' | System | 15 Oct 2020 17:01:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Oct 2020 11:59' | System | 15 Oct 2020 17:01:42 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 16 Oct 2020 18:16:32 |
| User entered 'Day 46' | System | 16 Oct 2020 18:16:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-18T12:29:13', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'de594703-8dca-4e3b-a855-73c38f075cec' User entered 'No (N)' | System | 18 Oct 2020 17:29:20 |
| | System | 18 Oct 2020 17:29:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-18T12:29:16', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'de594703-8dca-4e3b-a855-73c38f075cec' User entered '18 Oct 2020 12:29' | System | 18 Oct 2020 17:29:20 |
| | System | 18 Oct 2020 17:29:20 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '18 Oct 2020 12:00' | System | 16 Oct 2020 18:16:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Oct 2020 11:59' | System | 16 Oct 2020 18:16:32 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 17 Oct 2020 17:01:04 |
| User entered 'Day 47' | System | 17 Oct 2020 17:01:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-19T12:46:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '51483f71-2c38-4ec9-8be3-67c387c562c4' User entered 'No (N)' | System | 19 Oct 2020 17:52:59 |
| | System | 19 Oct 2020 17:52:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-19T12:46:31', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '51483f71-2c38-4ec9-8be3-67c387c562c4' User entered '19 Oct 2020 12:46' | System | 19 Oct 2020 17:52:59 |
| | System | 19 Oct 2020 17:52:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '19 Oct 2020 12:00' | System | 17 Oct 2020 17:01:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Oct 2020 11:59' | System | 17 Oct 2020 17:01:04 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 18 Oct 2020 17:28:27 |
| User entered 'Day 48' | System | 18 Oct 2020 17:28:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-21T08:50:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '78770362-560e-4484-9866-9489b6018b8c' User entered 'No (N)' | System | 21 Oct 2020 13:50:07 |
| | System | 21 Oct 2020 13:50:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-21T08:50:04', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '78770362-560e-4484-9866-9489b6018b8c' User entered '21 Oct 2020 08:50' | System | 21 Oct 2020 13:50:07 |
| | System | 21 Oct 2020 13:50:07 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '20 Oct 2020 12:00' | System | 18 Oct 2020 17:28:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Oct 2020 11:59' | System | 18 Oct 2020 17:28:27 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 19 Oct 2020 17:52:50 |
| User entered 'Day 49' | System | 19 Oct 2020 17:52:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T09:03:12', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '44794e91-ef7c-4ad1-a5bb-6d89960b853e' User entered 'No (N)' | System | 22 Oct 2020 14:03:17 |
| | System | 22 Oct 2020 14:03:17 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T09:03:15', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '44794e91-ef7c-4ad1-a5bb-6d89960b853e' User entered '22 Oct 2020 09:03' | System | 22 Oct 2020 14:03:17 |
| | System | 22 Oct 2020 14:03:17 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '21 Oct 2020 12:00' | System | 19 Oct 2020 17:52:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Oct 2020 11:59' | System | 19 Oct 2020 17:52:50 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 21 Oct 2020 13:50:19 |
| User entered 'Day 50' | System | 21 Oct 2020 13:50:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T12:48:48', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '1eac2b92-2755-498f-b759-f08e8eecb4ce' User entered 'No (N)' | System | 22 Oct 2020 17:48:56 |
| | System | 22 Oct 2020 17:48:56 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-22T12:48:51', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '1eac2b92-2755-498f-b759-f08e8eeeb4ce' User entered '22 Oct 2020 12:48' | System | 22 Oct 2020 17:48:56 |
| | System | 22 Oct 2020 17:48:56 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '22 Oct 2020 12:00' | System | 21 Oct 2020 13:50:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Oct 2020 11:59' | System | 21 Oct 2020 13:50:19 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 22 Oct 2020 14:03:03 |
| User entered 'Day 51' | System | 22 Oct 2020 14:03:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '23 Oct 2020 12:00' | System | 22 Oct 2020 14:03:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Oct 2020 11:59' | System | 22 Oct 2020 14:03:03 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 22 Oct 2020 17:48:39 |
| User entered 'Day 52' | System | 22 Oct 2020 17:48:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:49:36

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:49:36

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:49:36

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '24 Oct 2020 12:00' | System | 22 Oct 2020 17:48:39 |

US3452332

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 11 Aug 2021 22:49:36

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User entered '25 Oct 2020 11:59' | System | 22 Oct 2020 17:48:39 |

US3452332

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 16 Sep 2020 16:18:25 |

US3452332

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '11 Sep 2020' | Kim Calloway (b) (4) | 16 Sep 2020 16:18:25 |

US3452332

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Contact Made (CONTACT MADE)' | Kim Calloway (b) (4) | 16 Sep 2020 16:18:25 |

US3452332

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 16 Sep 2020 16:18:25 |

US3452332

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) April Green (b) (4) (b) (4) | 19 Sep 2020 05:16:49 |

US3452332

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'I' | System | 19 Sep 2020 05:16:49 |

US3452332

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) April Green (b) (4) (b) (4) | 19 Sep 2020 05:17:02 |

US3452332

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '18 Sep 2020' | (b) (4) April Green (b) (4) (b) (4) | 19 Sep 2020 05:17:02 |

US3452332

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) April Green (b) (4) (b) (4) | 19 Sep 2020 05:17:02 |

US3452332

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) April Green (b) (4) (b) (4) | 19 Sep 2020 05:17:02 |

US3452332

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) April Green (b) (4) (b) (4) | 25 Sep 2020 13:01:35 |

US3452332

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'I' | System | 25 Sep 2020 13:01:35 |

US3452332

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) April Green (b) (4) (b) (4) | 25 Sep 2020 13:01:45 |

US3452332

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '25 Sep 2020' | (b) (4) April Green (b) (4) (b) (4) | 25 Sep 2020 13:01:45 |

US3452332

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) April Green (b) (4) (b) (4) | 25 Sep 2020 13:01:45 |

US3452332

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) April Green (b) (4) (b) (4) | 25 Sep 2020 13:01:45 |

US3452332

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 30 Sep 2020 17:53:49 |

US3452332

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'I' | System | 30 Sep 2020 17:53:49 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 30 Sep 2020 17:54:01 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '30 Sep 2020' | (b) (4) Kim Calloway (b) (4) | 30 Sep 2020 17:54:01 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Clinic (Clinic)' | Kim Calloway (b) (4) | 30 Sep 2020 17:54:01 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User entered 'VISIT3' | System | 30 Sep 2020 17:54:01 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User entered empty. | System | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | (b) (4) Kim Calloway (b) (4) | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User entered empty. | System | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User entered empty. | System | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User entered empty. | System | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered empty. | Kim Calloway (b) (4) | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User entered empty. | System | 30 Sep 2020 17:54:07 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 30 Sep 2020 17:54:14 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '30 Sep 2020' | Kim Calloway (b) (4) | 30 Sep 2020 17:54:14 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 30 Sep 2020 17:54:27 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '30 Sep 2020' | (b) (4) Kim Calloway (b) (4) | 30 Sep 2020 17:54:27 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered '11:20' | (b) (4) Kim Calloway (b) (4) | 30 Sep 2020 17:54:27 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:21 |
| User entered '30 Sep 2020 11:20' | System | 30 Sep 2020 17:54:27 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Feb 2021 18:25:39 |
| User entered 'Yes (Y)' | (b) (4) Chalimar Rojo (b) (4) | 29 Oct 2020 15:47:03 |

US3452332

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'I' | System | 29 Oct 2020 15:47:03 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 64' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-07T00:16:04', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4082b263-675b-4e84-8a7a-252a50e62b88' | System | 07 Oct 2020 05:16:39 |
| User entered 'No (N)' | System | 07 Oct 2020 05:16:39 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-07T00:16:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4082b263-675b-4e84-8a7a-252a50e62b88' | System | 07 Oct 2020 05:16:39 |
| User entered 'No (N)' | System | 07 Oct 2020 05:16:39 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-07T00:16:36', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4082b263-675b-4e84-8a7a-252a50e62b88' User entered '07 Oct 2020 00:16:36' | System | 07 Oct 2020 05:16:39 |
| | System | 07 Oct 2020 05:16:39 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '07 Oct 2020 00:01' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '11 Oct 2020 23:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 71' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 13:18:56 |
| Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'SUBJECT NOTIFIED AND QUESTIONED ABOUT CHANGES TO HEALTH. SUBJECT DENIES CHANGES TO HEALTH AND DENIES CHANGES TO CON MEDS. STATED THIS ENTRY WAS ADDED IN ERROR.' (Site from DM). | April Green (b) (4) (b) (4) | 02 Nov 2020 18:03:27 |
| User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 18:15:20 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T00:02:54', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '910ed72e-f82a-4f63-89d8-c436259a029c' | System | 14 Oct 2020 19:44:08 |
| User entered 'Yes (Y)' | System | 14 Oct 2020 19:44:08 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T00:03:09', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '910ed72e-f82a-4f63-89d8-c436259a029c' | System | 14 Oct 2020 19:44:08 |
| User entered 'No (N)' | System | 14 Oct 2020 19:44:08 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T00:03:17', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '910ed72e-f82a-4f63-89d8-c436259a029c' | System | 14 Oct 2020 19:44:08 |
| User entered 'No (N)' | System | 14 Oct 2020 19:44:08 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T00:03:34', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '910ed72e-f82a-4f63-89d8-c436259a029c' | System | 14 Oct 2020 19:44:08 |
| User entered 'Yes (Y)' | System | 14 Oct 2020 19:44:08 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T14:42:56', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '910ed72e-f82a-4f63-89d8-c436259a029c' | System | 14 Oct 2020 19:44:08 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 14 Oct 2020 19:44:08 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-14T14:43:57', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '910ed72e-f82a-4f63-89d8-c436259a029c' User entered '14 Oct 2020 14:43:57' | System | 14 Oct 2020 19:44:08 |
| | System | 14 Oct 2020 19:44:08 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '14 Oct 2020 00:01' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '18 Oct 2020 23:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 78' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-21T08:49:14', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '71a85571-e987-4071-9f31-7e3d9b3093fa' User entered 'No (N)' | System | 21 Oct 2020 13:49:22 |
| | System | 21 Oct 2020 13:49:22 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-21T08:49:18', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '71a85571-e987-4071-9f31-7e3d9b3093fa' | System | 21 Oct 2020 13:49:22 |
| User entered 'No (N)' | System | 21 Oct 2020 13:49:22 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-10-21T08:49:20', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '71a85571-e987-4071-9f31-7e3d9b3093fa' User entered '21 Oct 2020 08:49:20' | System | 21 Oct 2020 13:49:22 |
| | System | 21 Oct 2020 13:49:22 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '21 Oct 2020 00:01' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '25 Oct 2020 23:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 92' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-04T07:57:49', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e076ed2a-c889-43a1-8b20-b974170ff473' User entered 'No (N)' | System | 04 Nov 2020 13:58:20 |
| | System | 04 Nov 2020 13:58:20 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-04T07:57:59', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e076ed2a-c889-43a1-8b20-b974170ff473' | System | 04 Nov 2020 13:58:20 |
| User entered 'No (N)' | System | 04 Nov 2020 13:58:20 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-04T07:58:15', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e076ed2a-c889-43a1-8b20-b974170ff473' User entered '04 Nov 2020 07:58:15' | System | 04 Nov 2020 13:58:20 |
| | System | 04 Nov 2020 13:58:20 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '04 Nov 2020 00:01' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '08 Nov 2020 23:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 99' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-11T17:53:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '154c8e2f-09f5-4523-ae10-e26a3de8bbc6' | System | 11 Nov 2020 23:54:00 |
| User entered 'No (N)' | System | 11 Nov 2020 23:54:00 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-11T17:53:50', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '154c8e2f-09f5-4523-ae10-e26a3de8bbc6' | System | 11 Nov 2020 23:54:00 |
| User entered 'No (N)' | System | 11 Nov 2020 23:54:00 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-11T17:53:57', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '154c8e2f-09f5-4523-ae10-e26a3de8bbc6' User entered '11 Nov 2020 17:53:57' | System | 11 Nov 2020 23:54:00 |
| | System | 11 Nov 2020 23:54:00 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '11 Nov 2020 00:01' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 20:24:59 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '15 Nov 2020 23:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered 'Day 106' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '18 Nov 2020 00:01' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:13:10 |
| Data entry locked. | System | 07 Aug 2020 20:41:30 |
| User entered '22 Nov 2020 23:59' | System | 07 Aug 2020 20:41:30 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-22T10:20:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4588e26e-5c5e-43de-a489-651fd44a017d' User entered 'No (N)' | System | 22 Nov 2020 16:21:18 |
| | System | 22 Nov 2020 16:21:18 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-22T10:21:01', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4588e26e-5c5e-43de-a489-651fd44a017d' User entered 'No (N)' | System | 22 Nov 2020 16:21:18 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-22T10:21:14', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '4588e26e-5c5e-43de-a489-651fd44a017d' User entered '22 Nov 2020 10:21:14' | System | 22 Nov 2020 16:21:18 |
| | System | 22 Nov 2020 16:21:18 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '22 Nov 2020 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '26 Nov 2020 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-29T10:01:24', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '104ebcea-5145-45f8-b7b5-f6b7b12d2c54' User entered 'No (N)' | System | 29 Nov 2020 16:03:05 |
| | System | 29 Nov 2020 16:03:05 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-29T10:02:25', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '104ebcea-5145-45f8-b7b5-f6b7b12d2c54' | System | 29 Nov 2020 16:03:05 |
| User entered 'No (N)' | System | 29 Nov 2020 16:03:05 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-11-29T10:02:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '104ebcea-5145-45f8-b7b5-f6b7b12d2c54' User entered '29 Nov 2020 10:02:33' | System | 29 Nov 2020 16:03:05 |
| | System | 29 Nov 2020 16:03:05 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '29 Nov 2020 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '03 Dec 2020 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-06T10:35:10', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ed97ca38-fc09-4caf-b54a-82f4f13b5cc1' | System | 06 Dec 2020 16:35:29 |
| User entered 'No (N)' | System | 06 Dec 2020 16:35:29 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-06T10:35:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ed97ca38-fc09-4caf-b54a-82f4f13b5cc1' User entered 'No (N)' | System | 06 Dec 2020 16:35:29 |
| | System | 06 Dec 2020 16:35:29 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-06T10:35:27', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ed97ca38-fc09-4caf-b54a-82f4f13b5cc1' User entered '06 Dec 2020 10:35:27' | System | 06 Dec 2020 16:35:29 |
| | System | 06 Dec 2020 16:35:29 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '06 Dec 2020 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '10 Dec 2020 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-13T16:52:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ffa27d48-41dd-48e5-8c01-402c491d6a69' | System | 13 Dec 2020 22:52:52 |
| User entered 'No (N)' | System | 13 Dec 2020 22:52:52 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-13T16:52:41', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ffa27d48-41dd-48e5-8c01-402c491d6a69' | System | 13 Dec 2020 22:52:52 |
| User entered 'No (N)' | System | 13 Dec 2020 22:52:52 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-13T16:52:47', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ffa27d48-41dd-48e5-8c01-402c491d6a69' User entered '13 Dec 2020 16:52:47' | System | 13 Dec 2020 22:52:52 |
| | System | 13 Dec 2020 22:52:52 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '13 Dec 2020 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '17 Dec 2020 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-20T00:02:18', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a39f1c08-54df-42e0-8b26-4e088cb0e7be' User entered 'No (N)' | System | 20 Dec 2020 06:03:31 |
| | System | 20 Dec 2020 06:03:31 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-20T00:02:34', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a39f1c08-54df-42e0-8b26-4e088cb0e7be' User entered 'Yes (Y)' | System | 20 Dec 2020 06:03:31 |
| | System | 20 Dec 2020 06:03:31 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Please 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-20T00:03:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a39f1c08-54df-42e0-8b26-4e088cb0e7be' | System | 20 Dec 2020 06:03:31 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 20 Dec 2020 06:03:31 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-20T00:03:22', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'a39f1c08-54df-42e0-8b26-4e088cb0e7be' User entered '20 Dec 2020 00:03:22' | System | 20 Dec 2020 06:03:31 |
| | System | 20 Dec 2020 06:03:31 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '20 Dec 2020 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '24 Dec 2020 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-27T08:02:44', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '803b3248-90b1-4cf3-b21a-b5cc8b99d37d' | System | 27 Dec 2020 14:03:06 |
| User entered 'No (N)' | System | 27 Dec 2020 14:03:06 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-27T08:02:53', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '803b3248-90b1-4cf3-b21a-b5cc8b99d37d' | System | 27 Dec 2020 14:03:06 |
| User entered 'No (N)' | System | 27 Dec 2020 14:03:06 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2020-12-27T08:03:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '803b3248-90b1-4cf3-b21a-b5cc8b99d37d' User entered '27 Dec 2020 08:03:00' | System | 27 Dec 2020 14:03:06 |
| | System | 27 Dec 2020 14:03:06 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '27 Dec 2020 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '31 Dec 2020 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-03T00:02:42', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'fa95887b-5108-4e14-9af2-df7bcace775c' User entered 'No (N)' | System | 03 Jan 2021 06:03:34 |
| | System | 03 Jan 2021 06:03:34 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-03T00:03:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'fa95887b-5108-4e14-9af2-df7bcace775c' | System | 03 Jan 2021 06:03:34 |
| User entered 'No (N)' | System | 03 Jan 2021 06:03:34 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-03T00:03:31', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'fa95887b-5108-4e14-9af2-df7bcace775c' User entered '03 Jan 2021 00:03:31' | System | 03 Jan 2021 06:03:34 |
| | System | 03 Jan 2021 06:03:34 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '03 Jan 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '07 Jan 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-10T11:09:52', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'd43a0ff1-a561-423b-9470-d814b8c455c2' | System | 10 Jan 2021 16:10:30 |
| User entered 'No (N)' | System | 10 Jan 2021 16:10:30 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-10T11:10:19', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'd43a0ff1-a561-423b-9470-d814b8c455c2' | System | 10 Jan 2021 16:10:30 |
| User entered 'No (N)' | System | 10 Jan 2021 16:10:30 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-10T11:10:23', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'd43a0ff1-a561-423b-9470-d814b8c455c2' User entered '10 Jan 2021 11:10:23' | System | 10 Jan 2021 16:10:30 |
| | System | 10 Jan 2021 16:10:30 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '10 Jan 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '14 Jan 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-17T07:37:33', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2914d8b3-3667-4da6-a4c0-ebdcc1791817' | System | 17 Jan 2021 13:37:56 |
| User entered 'No (N)' | System | 17 Jan 2021 13:37:56 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-17T07:37:38', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2914d8b3-3667-4da6-a4c0-ebdcc1791817' | System | 17 Jan 2021 13:37:56 |
| User entered 'No (N)' | System | 17 Jan 2021 13:37:56 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-17T07:37:51', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '2914d8b3-3667-4da6-a4c0-ebdcc1791817' | System | 17 Jan 2021 13:37:56 |
| User entered '17 Jan 2021 07:37:51' | System | 17 Jan 2021 13:37:56 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '17 Jan 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '21 Jan 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-24T00:02:21', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e10957e8-812e-4a4b-bf56-ba2471b9cc42' | System | 24 Jan 2021 06:02:57 |
| User entered 'No (N)' | System | 24 Jan 2021 06:02:57 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-24T00:02:32', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e10957e8-812e-4a4b-bf56-ba2471b9cc42' | System | 24 Jan 2021 06:02:57 |
| User entered 'No (N)' | System | 24 Jan 2021 06:02:57 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-24T00:02:43', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'e10957e8-812e-4a4b-bf56-ba2471b9cc42' User entered '24 Jan 2021 00:02:43' | System | 24 Jan 2021 06:02:57 |
| | System | 24 Jan 2021 06:02:57 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '24 Jan 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '28 Jan 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-31T08:17:54', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '73a94fdd-0a6e-4a5b-b282-306c907d1903' | System | 31 Jan 2021 14:18:13 |
| User entered 'No (N)' | System | 31 Jan 2021 14:18:13 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-31T08:18:03', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '73a94fdd-0a6e-4a5b-b282-306c907d1903' | System | 31 Jan 2021 14:18:13 |
| User entered 'No (N)' | System | 31 Jan 2021 14:18:13 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-01-31T08:18:10', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '73a94fdd-0a6e-4a5b-b282-306c907d1903' User entered '31 Jan 2021 08:18:10' | System | 31 Jan 2021 14:18:13 |
| | System | 31 Jan 2021 14:18:13 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '31 Jan 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '04 Feb 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-07T05:34:10', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ac7fc3b8-1f00-4730-abc3-44d12bfafe99' | System | 07 Feb 2021 12:34:27 |
| User entered 'No (N)' | System | 07 Feb 2021 12:34:27 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-07T05:34:15', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ac7fc3b8-1f00-4730-abc3-44d12bfafe99' | System | 07 Feb 2021 12:34:27 |
| User entered 'No (N)' | System | 07 Feb 2021 12:34:27 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-07T05:34:25', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'ac7fc3b8-1f00-4730-abc3-44d12bfafe99' | System | 07 Feb 2021 12:34:27 |
| User entered '07 Feb 2021 05:34:25' | System | 07 Feb 2021 12:34:27 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '07 Feb 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '11 Feb 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-14T03:21:31', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '94f7a6ec-3796-459c-8554-82df3b46c4d3' User entered 'No (N)' | System | 14 Feb 2021 10:21:46 |
| | System | 14 Feb 2021 10:21:46 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-14T03:21:39', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '94f7a6ec-3796-459c-8554-82df3b46c4d3' | System | 14 Feb 2021 10:21:46 |
| User entered 'No (N)' | System | 14 Feb 2021 10:21:46 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-14T03:21:43', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '94f7a6ec-3796-459c-8554-82df3b46c4d3' User entered '14 Feb 2021 03:21:43' | System | 14 Feb 2021 10:21:46 |
| | System | 14 Feb 2021 10:21:46 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '14 Feb 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '18 Feb 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-21T08:03:58', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'dafbb9f6-d1ec-4121-b5b3-02155b94f834' | System | 21 Feb 2021 14:04:09 |
| User entered 'No (N)' | System | 21 Feb 2021 14:04:09 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-21T08:04:03', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'dafbb9f6-d1ec-4121-b5b3-02155b94f834' User entered 'No (N)' | System | 21 Feb 2021 14:04:09 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-21T08:04:07', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: 'dafbb9f6-d1ec-4121-b5b3-02155b94f834' | System | 21 Feb 2021 14:04:09 |
| User entered '21 Feb 2021 08:04:07' | System | 21 Feb 2021 14:04:09 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '21 Feb 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '25 Feb 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-28T07:49:37-06:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '26c3210e-31f8-4bbc-8e96-4ab989c0db66' | System | 28 Feb 2021 13:50:01 |
| User entered 'No (N)' | System | 28 Feb 2021 13:50:01 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-28T07:49:50-06:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '26c3210e-31f8-4bbc-8e96-4ab989c0db66' | System | 28 Feb 2021 13:50:01 |
| User entered 'No (N)' | System | 28 Feb 2021 13:50:01 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-28T07:49:58-06:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '26c3210e-31f8-4bbc-8e96-4ab989c0db66' | System | 28 Feb 2021 13:50:01 |
| User entered '28 Feb 2021 07:49:58' | System | 28 Feb 2021 13:50:01 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '28 Feb 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '04 Mar 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-10T04:46:46-06:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '86a02d74-60d9-42cd-99e8-15e3b3856831' | System | 10 Mar 2021 10:47:03 |
| User entered 'No (N)' | System | 10 Mar 2021 10:47:03 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-10T04:46:52-06:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '86a02d74-60d9-42cd-99e8-15e3b3856831' | System | 10 Mar 2021 10:47:03 |
| User entered 'No (N)' | System | 10 Mar 2021 10:47:03 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-10T04:46:56-06:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '86a02d74-60d9-42cd-99e8-15e3b3856831' | System | 10 Mar 2021 10:47:03 |
| User entered '10 Mar 2021 04:46:56' | System | 10 Mar 2021 10:47:03 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '07 Mar 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '11 Mar 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-14T08:59:27-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '25e29177-13c5-4dba-8704-a683f6f20a2c' | System | 14 Mar 2021 13:59:41 |
| User entered 'No (N)' | System | 14 Mar 2021 13:59:41 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-14T08:59:34-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '25e29177-13c5-4dba-8704-a683f6f20a2c' | System | 14 Mar 2021 13:59:41 |
| User entered 'No (N)' | System | 14 Mar 2021 13:59:41 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-14T08:59:39-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '25e29177-13c5-4dba-8704-a683f6f20a2c' User entered '14 Mar 2021 08:59:39' | System | 14 Mar 2021 13:59:41 |
| | System | 14 Mar 2021 13:59:41 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '14 Mar 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '18 Mar 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-21T00:02:34-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '885d89d2-6838-466d-9074-43f70187ce36' | System | 21 Mar 2021 05:03:19 |
| User entered 'No (N)' | System | 21 Mar 2021 05:03:19 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-21T00:02:43-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '885d89d2-6838-466d-9074-43f70187ce36' | System | 21 Mar 2021 05:03:19 |
| User entered 'No (N)' | System | 21 Mar 2021 05:03:19 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-21T00:02:46-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '885d89d2-6838-466d-9074-43f70187ce36' | System | 21 Mar 2021 05:03:19 |
| User entered '21 Mar 2021 00:02:46' | System | 21 Mar 2021 05:03:19 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '21 Mar 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '25 Mar 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-28T00:02:51-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '3faaa5c8-7ca5-49a9-9091-c046e92ace2c' | System | 28 Mar 2021 05:03:04 |
| User entered 'No (N)' | System | 28 Mar 2021 05:03:04 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-28T00:02:57-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '3faaa5c8-7ca5-49a9-9091-c046e92ace2c' | System | 28 Mar 2021 05:03:04 |
| User entered 'No (N)' | System | 28 Mar 2021 05:03:04 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-03-28T00:03:00-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '3faaa5c8-7ca5-49a9-9091-c046e92ace2c' User entered '28 Mar 2021 00:03:00' | System | 28 Mar 2021 05:03:04 |
| | System | 28 Mar 2021 05:03:04 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '28 Mar 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '01 Apr 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-04T00:43:42-04:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9e794631-5671-40c9-84ba-986e955d3dc1' User entered 'No (N)' | System | 04 Apr 2021 04:43:53 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-04T00:43:47-04:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9e794631-5671-40c9-84ba-986e955d3dc1' | System | 04 Apr 2021 04:43:53 |
| User entered 'No (N)' | System | 04 Apr 2021 04:43:53 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-04T00:43:51-04:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9e794631-5671-40c9-84ba-986e955d3dc1' | System | 04 Apr 2021 04:43:53 |
| User entered '04 Apr 2021 00:43:51' | System | 04 Apr 2021 04:43:53 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '04 Apr 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '08 Apr 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-11T06:31:50-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '92f26c8e-3040-4910-8269-3d6cb1340e0c' | System | 11 Apr 2021 11:32:00 |
| User entered 'No (N)' | System | 11 Apr 2021 11:32:00 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-11T06:31:55-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '92f26c8e-3040-4910-8269-3d6cb1340e0c' | System | 11 Apr 2021 11:32:00 |
| User entered 'No (N)' | System | 11 Apr 2021 11:32:00 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-11T06:31:58-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '92f26c8e-3040-4910-8269-3d6cb1340e0c' | System | 11 Apr 2021 11:32:00 |
| User entered '11 Apr 2021 06:31:58' | System | 11 Apr 2021 11:32:00 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '11 Apr 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '15 Apr 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-19T05:36:08-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '28cf511e-7a60-4c01-9632-06ab3e100a0f' | System | 19 Apr 2021 10:36:22 |
| User entered 'No (N)' | System | 19 Apr 2021 10:36:22 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-19T05:36:13-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '28cf511e-7a60-4c01-9632-06ab3e100a0f' | System | 19 Apr 2021 10:36:22 |
| User entered 'No (N)' | System | 19 Apr 2021 10:36:22 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-19T05:36:16-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '28cf511e-7a60-4c01-9632-06ab3e100a0f' | System | 19 Apr 2021 10:36:22 |
| User entered '19 Apr 2021 05:36:16' | System | 19 Apr 2021 10:36:22 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '18 Apr 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '22 Apr 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-25T00:38:27-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8a658950-2959-45da-af12-b514171709fc' | System | 25 Apr 2021 05:38:43 |
| User entered 'No (N)' | System | 25 Apr 2021 05:38:43 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

Have you been exposed to someone with 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 (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-25T00:38:30-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8a658950-2959-45da-af12-b514171709fc' User entered 'No (N)' | System | 25 Apr 2021 05:38:43 |
| | System | 25 Apr 2021 05:38:43 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-04-25T00:38:41-05:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '8a658950-2959-45da-af12-b514171709fc' User entered '25 Apr 2021 00:38:41' | System | 25 Apr 2021 05:38:43 |
| | System | 25 Apr 2021 05:38:43 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '25 Apr 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '29 Apr 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '02 May 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '06 May 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '09 May 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '13 May 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '16 May 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '20 May 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '23 May 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '27 May 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '30 May 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '03 Jun 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '06 Jun 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '10 Jun 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '13 Jun 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '17 Jun 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '20 Jun 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '24 Jun 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '27 Jun 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '01 Jul 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '04 Jul 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '08 Jul 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '11 Jul 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '15 Jul 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '18 Jul 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '22 Jul 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '25 Jul 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '29 Jul 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '01 Aug 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '05 Aug 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '08 Aug 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '12 Aug 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '15 Aug 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '19 Aug 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '22 Aug 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '26 Aug 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '29 Aug 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '02 Sep 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '05 Sep 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '09 Sep 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '12 Sep 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '16 Sep 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '19 Sep 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '23 Sep 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '26 Sep 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '30 Sep 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '03 Oct 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '07 Oct 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '10 Oct 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '14 Oct 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '17 Oct 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '21 Oct 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '24 Oct 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '28 Oct 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '31 Oct 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '04 Nov 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '07 Nov 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '11 Nov 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '14 Nov 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '18 Nov 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '21 Nov 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '25 Nov 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '28 Nov 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '02 Dec 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '05 Dec 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '09 Dec 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '12 Dec 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '16 Dec 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '19 Dec 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '23 Dec 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '26 Dec 2021 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '30 Dec 2021 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '02 Jan 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '06 Jan 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '09 Jan 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '13 Jan 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '16 Jan 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '20 Jan 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '23 Jan 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '27 Jan 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '30 Jan 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '03 Feb 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '06 Feb 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '10 Feb 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '13 Feb 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '17 Feb 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '20 Feb 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '24 Feb 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '27 Feb 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '03 Mar 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '06 Mar 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '10 Mar 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '13 Mar 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '17 Mar 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '20 Mar 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '24 Mar 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '27 Mar 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '31 Mar 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '03 Apr 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '07 Apr 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '10 Apr 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '14 Apr 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '17 Apr 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '21 Apr 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '24 Apr 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '28 Apr 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '01 May 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '05 May 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '08 May 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '12 May 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '15 May 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '19 May 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '22 May 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '26 May 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '29 May 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '02 Jun 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '05 Jun 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '09 Jun 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '12 Jun 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '16 Jun 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '19 Jun 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '23 Jun 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '26 Jun 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '30 Jun 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '03 Jul 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '07 Jul 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '10 Jul 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '14 Jul 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '17 Jul 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '21 Jul 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '24 Jul 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '28 Jul 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '31 Jul 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '04 Aug 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '07 Aug 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '11 Aug 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '14 Aug 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '18 Aug 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '21 Aug 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '25 Aug 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '28 Aug 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '01 Sep 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '04 Sep 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '08 Sep 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '11 Sep 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '15 Sep 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '18 Sep 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '22 Sep 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '25 Sep 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '29 Sep 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '02 Oct 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '06 Oct 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '09 Oct 2022 00:01' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:36

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:13:10 |
| Amendment Manager: User entered '13 Oct 2022 23:59' | System | 19 Nov 2020 16:13:10 |

US3452332

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:49:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-27T21:13:30-06:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9a064a69-f391-4eda-a81c-55952fa50ba0' | System | 28 Feb 2021 03:15:42 |
| User entered 'No (N)' | System | 28 Feb 2021 03:15:42 |

US3452332

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:49:36

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 12:31:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86C4708A-3336-4883-8D07-5DFD6F009898)', Time: '2021-02-27T21:13:37-06:00', User OID: 'PatientReportedOutcome (US3452332)', ODM File OID: '9a064a69-f391-4eda-a81c-55952fa50ba0' User entered '28 Feb 2021 03:13:37' | System | 28 Feb 2021 03:15:42 |
| | System | 28 Feb 2021 03:15:42 |

US3452332

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 29 Oct 2020 15:47:15 |

US3452332

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '29 Oct 2020' | Chalimar Rojo (b) (4) | 29 Oct 2020 15:47:15 |

US3452332

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Contact Made (CONTACT MADE)' | Chalimar Rojo (b) (4) | 29 Oct 2020 15:47:15 |

US3452332

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | Chalimar Rojo (b) (4) | 29 Oct 2020 15:47:15 |

US3452332

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 29 Oct 2020 15:47:20 |

US3452332

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:43:16 |
| User entered 'I' | System | 29 Oct 2020 15:47:20 |

US3452332

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 03 Dec 2020 21:10:13 |

US3452332

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '2 Dec 2020' | Chalimar Rojo (b) (4) | 03 Dec 2020 21:10:13 |

US3452332

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Contact Made (CONTACT MADE)' | Chalimar Rojo (b) (4) | 03 Dec 2020 21:10:13 |

US3452332

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | Chalimar Rojo (b) (4) | 03 Dec 2020 21:10:13 |

US3452332

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 05 Jan 2021 18:08:40 |

US3452332

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User entered 'I' | System | 05 Jan 2021 18:08:40 |

US3452332

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 05 Jan 2021 18:08:53 |

US3452332

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 03:51:18 |
| Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'date correct as entered ' (Site from System). | Chalimar Rojo (b) (4) (b) (4) | 05 Jan 2021 18:08:58 |
| User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System). | System | 05 Jan 2021 18:08:53 |
| User entered '5 Jan 2021' | Chalimar Rojo (b) (4) (b) (4) | 05 Jan 2021 18:08:53 |

US3452332

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Contact Made (CONTACT MADE)' | Chalimar Rojo (b) (4) | 05 Jan 2021 18:08:53 |

US3452332

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | Chalimar Rojo (b) (4) | 05 Jan 2021 18:08:53 |

US3452332

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 04 Feb 2021 14:17:42 |

US3452332

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User entered 'I' | System | 04 Feb 2021 14:17:42 |

US3452332

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 04 Feb 2021 14:17:55 |

US3452332

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 15:31:58 |
| Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as entered' (Site from System). | Chalimar Rojo (b) (4) (b) (4) | 04 Feb 2021 14:18:04 |
| User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 04 Feb 2021 14:17:55 |
| User entered '4 Feb 2021' | Chalimar Rojo (b) (4) (b) (4) | 04 Feb 2021 14:17:55 |

US3452332

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Contact Made (CONTACT MADE)' | Chalimar Rojo (b) (4) | 04 Feb 2021 14:17:55 |

US3452332

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | Chalimar Rojo (b) (4) | 04 Feb 2021 14:17:55 |

US3452332

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Destiny Heinzig-Cartwright (b) (4) | 08 Feb 2021 18:07:58 |

US3452332

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:40:07 |
| User entered '1' | System | 08 Feb 2021 18:07:58 |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 3 Mar 2021. However, the data on the Vital signs forms at this visit is blank and the other visit, data is recorded. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please reconcile. Thank you!' (Site from DM). | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 14:10:14 |
| Query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 3 Mar 2021. However, the data on the Vital signs forms at this visit is blank and the other visit, data is recorded. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please reconcile. Thank you!' answered with 'vitals are not done on visit 4 day 209' (Site from DM). | Kim Calloway (b) (4) (b) (4) | 30 Mar 2021 12:58:59 |
| User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 3 Mar 2021. However, the data on the Vital signs forms at this visit is blank and the other visit, data is recorded. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please reconcile. Thank you!' (Site from DM). | (b) (4), (b) (6) | 30 Mar 2021 12:46:17 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) (b) (4) | 03 Mar 2021 19:13:02 |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered '03 Mar 2021' | Kim Calloway (b) (4) | 03 Mar 2021 19:13:02 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Kim Calloway (b) (4) | 03 Mar 2021 19:13:02 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User entered 'VISIT4' | System | 03 Mar 2021 19:13:02 |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'No (N)' | Kim Calloway (b) (4) | 30 Mar 2021 12:58:31 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 30 Mar 2021 12:58:31 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 30 Mar 2021 12:58:31 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User entered empty. | System | 30 Mar 2021 12:58:31 |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 30 Mar 2021 12:58:31 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 30 Mar 2021 12:58:31 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 30 Mar 2021 12:58:31 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 30 Mar 2021 12:58:31 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User entered empty. | System | 30 Mar 2021 12:58:31 |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 30 Mar 2021 12:58:31 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User entered empty. | System | 30 Mar 2021 12:58:31 |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 30 Mar 2021 12:58:31 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User entered empty. | System | 30 Mar 2021 12:58:31 |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 30 Mar 2021 12:58:31 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User entered empty. | System | 30 Mar 2021 12:58:31 |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| | | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| | | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Mar 2021 19:13:09 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered '03 Mar 2021' | Kim Calloway (b) (4) | 03 Mar 2021 19:13:09 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Mar 2021 19:13:23 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered '03 Mar 2021' | Kim Calloway (b) (4) | 03 Mar 2021 19:13:23 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered '11:54' | Kim Calloway (b) (4) | 03 Mar 2021 19:13:23 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User entered '03 Mar 2021 11:54' | System | 03 Mar 2021 19:13:23 |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Mar 2021 19:13:28 |
| | (b) (4) | |

US3452332

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:44:42 |
| | | |
| User entered '1' | System | 03 Mar 2021 19:13:28 |

US3452332

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 05 Apr 2021 19:45:24 |
| | (b) (4) | |

US3452332

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 12:29:13 |
| Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as entered ' (Site from System). | Chalimar Rojo (b) (4) (b) (4) | 05 Apr 2021 19:45:32 |
| User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 05 Apr 2021 19:45:24 |
| User entered '5 Apr 2021' | Chalimar Rojo (b) (4) (b) (4) | 05 Apr 2021 19:45:24 |

US3452332

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Chalimar Rojo (b) (4) | 05 Apr 2021 19:45:24 |
| | (b) (4) | |

US3452332

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Chalimar Rojo (b) (4) | 05 Apr 2021 19:45:24 |
| | (b) (4) | |

US3452332

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 05 Apr 2021 19:45:14 |
| | (b) (4) | |

US3452332

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Apr 2021 19:45:14 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:36

[Date of Contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:08 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:09:25 |
| Query 'Please confirm that a illness visit should be generated (day of nasal swap) .' canceled (Site from CRA). | (b) (4), (b) (6) | 05 Nov 2020 22:09:23 |
| User opened query 'Please confirm that a illness visit should be generated (day of nasal swap) .' (Site from CRA). | (b) (4), (b) (6) | 05 Nov 2020 20:46:00 |
| User entered '26 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:00:29 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:36

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:08 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:09:25 |
| User entered '12:45' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:00:29 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:36

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:08 |
| User entered '26 Oct 2020 12:45' | System | 05 Nov 2020 20:00:29 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:36

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:08 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:32:09 |
| User closed query 'Per ETRTR: Please consider updating to "Clinic Visit - Unscheduled" due to visit not occurring at a Protocol Scheduled Visit, thanks.' (Site from CRA). | (b) (4), (b) (6) | 07 Nov 2020 15:39:04 |
| Query 'Per ETRTR: Please consider updating to "Clinic Visit - Unscheduled" due to visit not occurring at a Protocol Scheduled Visit, thanks.' answered with '.' (Site from CRA). | Kim Hamilton (b) (4) | 06 Nov 2020 20:22:32 |
| DataPoint Un-verified. | Kim Hamilton (b) (4) | 06 Nov 2020 20:22:27 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error | Kim Hamilton (b) (4) | 06 Nov 2020 20:22:27 |
| User opened query 'Per ETRTR: Please consider updating to "Clinic Visit - Unscheduled" due to visit not occurring at a Protocol Scheduled Visit, thanks.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 18:59:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:25 |
| User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' | - April Green (b) (4) (b) (4) | 05 Nov 2020 20:00:29 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:36

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:08 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:09:25 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:00:29 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 1 (Day 1)' | (b) (4) April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| User closed query 'Re-query: Please consider adding 24Oct20 and 25Oct20 as Day 1 and Day 2. Per CCG's and training provided to sites notes that the Day 1 on symptom log is the actual day symptoms began. When 24Oct and 25Oct are added the symptom days of all remaining entries will need to be updated to the corresponding symptom day as they should match sequentially.' (Site from CRA). | (b) (4), (b) (6) | 09 Nov 2020 19:32:55 |
| Query 'Re-query: Please consider adding 24Oct20 and 25Oct20 as Day 1 and Day 2. Per CCG's and training provided to sites notes that the Day 1 on symptom log is the actual day symptoms began. When 24Oct and 25Oct are added the symptom days of all remaining entries will need to be updated to the corresponding symptom day as they should match sequentially.' answered with 'SITE DOES NOT HAVE ALLK REQUIRED INFOMRTION FOR 10/24 AND 10/25. 10/26/2020 IS THE DAT THAT THE SUBJECTS CAME IN FOR VISIT. ' (Site from CRA). | April Green (b) (4) (b) (4) | 09 Nov 2020 14:04:49 |
| User opened query 'Re-query: Please consider adding 24Oct20 and 25Oct20 as Day 1 and Day 2. Per CCG's and training provided to sites notes that the Day 1 on symptom log is the actual day symptoms began. When 24Oct and 25Oct are added the symptom days of all remaining entries will need to be updated to the corresponding symptom day as they should match sequentially.' (Site from CRA). | (b) (4), (b) (6) | 07 Nov 2020 15:40:55 |
| User closed query 'Per ETRTR: According to COVID AE page, Start date was 24Oct20. Please confirm and add symptoms 25Oct20 as applicable, thanks.' (Site from CRA). | (b) (4), (b) (6) | 07 Nov 2020 15:40:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Query 'Per ETRTR: According to COVID AE page, Start date was 24Oct20. Please confirm and add symptoms 25Oct20 as applicable, thanks.' answered with 'information added for 10/25/2020' (Site from CRA). | Kim Hamilton (b) (4) | 06 Nov 2020 20:29:05 |
| User opened query 'Per ETRTR: According to COVID AE page, Start date was 24Oct20. Please confirm and add symptoms 25Oct20 as applicable, thanks.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 19:11:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '26 Oct 2020' | April Green (b) (4) | 05 Nov 2020 20:06:59 |
| | (b) (4) | |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '0' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '98' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '98.7' F | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:06:59 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 2 (Day 2)' | (b) (4) April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '27 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '0' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '97' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '98.7' F | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:08:13 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 3 (Day 3)' | (b) (4) April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '28 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '0' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '94' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '99.3' F | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 4 (Day 4)' | (b) (4) April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '29 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '0' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '94' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '99.5' F | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:09:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 5 (Day 5)' | (b) (4) April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '30 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '0' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '97' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '101.2' F | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:10:55 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 6 (Day 6)' | (b) (4) April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '31 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '0' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '91' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '101.2' F | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:12:17 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 7 (Day 7)' | (b) (4) April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '01 Nov 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '0' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '96' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '100.4' F | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:13:47 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 8 (Day 8)' | (b) (4) April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '02 Nov 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '0' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '97' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '99.3' F | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Moderate (Moderate)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:15:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 9 (Day 9)' | (b) (4) April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '03 Nov 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '0' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| Query 'Per CDM re-query: Previous query should have read "record is less than or equal to 93% O2. Please make all appropriate udpates." ' canceled (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 15:32:37 |
| User opened query 'Per CDM re-query: Previous query should have read "record is less than or equal to 93% O2. Please make all appropriate udpates." ' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 14:41:01 |
| User closed query 'Per CDM: record is </=93% O2. Please make all appropriate udpates.' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 14:41:01 |
| Query 'Per CDM: record is </=93% O2. Please make all appropriate udpates.' answered with 'RECORD IS WHAT?' (Site from DM). | April Green (b) (4) (b) (4) | 09 Nov 2020 14:08:55 |
| User opened query 'Per CDM: record is </=93% O2. Please make all appropriate udpates.' (Site from DM). | (b) (4), (b) (6) | 09 Nov 2020 04:35:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '93' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '97.3' F | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:16:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 10 (Day 10)' | (b) (4) April Green (b) (4) | 05 Nov 2020 20:17:31 |
| | (b) (4) | |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '04 Nov 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '0' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '97' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '98.3' F | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:17:31 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 11 (Day 11)' | (b) (4) April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '05 Nov 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '0' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '97' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered '97.6' F | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:09:51 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:18:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 12 (Day 12)' | (b) (4) April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '06 Nov 2020' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '0' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '95' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '96.2' F | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 06 Nov 2020 16:15:38 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 13 (Day 13)' | (b) (4) April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '7 Nov 2020' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '0' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '97' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '98.4' F | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:00 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 14 (Day 14)' | (b) (4) April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '8 Nov 2020' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '0' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '97' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '97.9' F | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:23:54 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 15 (Day 15)' | (b) (4) April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '9 Nov 2020' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '0' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '97' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered '97.8' F | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 19:32:36 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 09 Nov 2020 17:24:46 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 16 (Day 16)' | (b) (4) April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '10 Nov 2020' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '0' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '96' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '97.0' F | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 10 Nov 2020 23:02:35 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 17 (Day 17)' | (b) (4) April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '11 Nov 2020' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '0' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '99' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '97.9' F | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 11 Nov 2020 21:41:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 18 (Day 18)' | (b) (4) April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '12 Nov 2020' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '0' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '97' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '97.9' F | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 12 Nov 2020 22:00:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 19 (Day 19)' | (b) (4) April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '13 Nov 2020' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '0' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '97' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '98.3' F | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'Mild (Mild)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 13 Nov 2020 17:06:20 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 20 (Day 20)' | (b) (4) April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '14 Nov 2020' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '0' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '98' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '98.7' F | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:01:25 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 21 (Day 21)' | (b) (4) April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '15 Nov 2020' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '0' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '98' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '98.3' F | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:02:03 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 22 (Day 22)' | (b) (4) April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '16 Nov 2020' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '0' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '97' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered '97.9' F | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Nov 2020 20:16:44 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 16 Nov 2020 19:03:16 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Per CDM: Per sponsor review, please verify 'Symptom Days'. Since site has already recorded 'Day 24' as '18Nov2020', please consider updating this form to 'Day 23' for '17Nov2020'.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 13:46:24 |
| Query 'Per CDM: Per sponsor review, please verify 'Symptom Days'. Since site has already recorded 'Day 24' as '18Nov2020', please consider updating this form to 'Day 23' for '17Nov2020'.' answered with 'updated' (Site from DM). | Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 20:16:24 |
| User entered 'Day 23 (Day 23)' reason for change: Data Entry Error | Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 20:16:09 |
| User opened query 'Per CDM: Per sponsor review, please verify 'Symptom Days'. Since site has already recorded 'Day 24' as '18Nov2020', please consider updating this form to 'Day 23' for '17Nov2020'.' (Site from DM). | (b) (4), (b) (6) | 14 Mar 2021 21:45:07 |
| User entered 'Day 24 (Day 24)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '17 Nov 2020' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '0' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '98' reason for change: Data Entry Error | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:02 |
| User entered '98.3' (non-conformant). | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 18 Nov 2020 21:04:02 |
| User entered empty. | System | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '97.7' F | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:03:39 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 24 (Day 24)' | (b) (4) April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '18 Nov 2020' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '0' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '98' reason for change: Data Entry Error | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:37 |
| User entered '98.3' (non-conformant). | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 18 Nov 2020 21:04:37 |
| User entered empty. | System | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '97.6' F | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:51:44 |
| User closed query 'Per source, subject did not experience nasal congestion. Please Reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 16 Dec 2020 18:51:41 |
| Query 'Per source, subject did not experience nasal congestion. Please Reconcile. ' answered with 'added' (Site from CRA). | April Green (b) (4) (b) (4) | 16 Dec 2020 18:41:20 |
| DataPoint Un-verified. | April Green (b) (4) (b) (4) | 16 Dec 2020 18:41:11 |
| User entered 'None (None)' reason for change: Data Entry Error | April Green (b) (4) (b) (4) | 16 Dec 2020 18:41:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Dec 2020 18:02:33 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User opened query 'Per source, subject did not experience nasal congestion. Please Reconcile. ' (Site from CRA). | (b) (4), (b) (6) | 02 Dec 2020 21:45:23 |
| User entered empty. | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 18 Nov 2020 21:04:27 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 25 (Day 25)' | (b) (4) April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '19 Nov 2020' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '0' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '98' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '97.9' F | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 19 Nov 2020 16:42:51 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 26 (Day 26)' | (b) (4) April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '20 Nov 2020' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '0' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '97' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '98.1' F | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 20 Nov 2020 13:51:32 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 27 (Day 27)' | (b) (4) April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '21 Nov 2020' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '0' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '98' reason for change: Data Entry Error | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:49 |
| User entered '98.' (non-conformant). | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 23 Nov 2020 19:14:49 |
| User entered empty. | System | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '97.6' F | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:14:41 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Day 28 (Day 28)' | (b) (4) April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '22 Nov 2020' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '0' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '98' reason for change: Data Entry Error | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:50 |
| User entered '98.3' (non-conformant). | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User entered '%' | System | 23 Nov 2020 19:15:50 |
| User entered empty. | System | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered '98.3' F | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:49:36

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:30 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 18:44:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Apr 2021 17:27:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 21:46:30 |
| User entered 'None (None)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:15:28 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:49:36

[Date of Visit](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Please confirm date of visit as lab portal shows site entered Illness Day 1 collection on 28Oct2020' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:33:08 |
| Query 'Please confirm date of visit as lab portal shows site entered Illness Day 1 collection on 28Oct2020' answered with 'DATE IS CORRECT' (Site from CRA). | April Green (b) (4) (b) (4) | 09 Nov 2020 13:58:03 |
| User opened query 'Please confirm date of visit as lab portal shows site entered Illness Day 1 collection on 28Oct2020' (Site from CRA). | (b) (4), (b) (6) | 07 Nov 2020 15:43:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:10:06 |
| User entered '26 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:44:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:49:36

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:06 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:44:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:49:36

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). | (b) (4) (b) (4), (b) (6) | 06 Nov 2020 10:42:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:10:06 |
| Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with '.' (Site from System). | April Green (b) (4) (b) (4) | 05 Nov 2020 20:45:22 |
| User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). | System | 05 Nov 2020 20:44:48 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:44:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:49:36

[Date of Test](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Re-query: Please confirm date of visit and date of test as lab portal shows site entered Illness Day 1 collection on 28Oct2020' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:33:10 |
| Query 'Re-query: Please confirm date of visit and date of test as lab portal shows site entered Illness Day 1 collection on 28Oct2020' answered with 'DATE IS CORRECT' (Site from CRA). | April Green (b) (4) (b) (4) | 09 Nov 2020 13:58:42 |
| User opened query 'Re-query: Please confirm date of visit and date of test as lab portal shows site entered Illness Day 1 collection on 28Oct2020' (Site from CRA). | (b) (4), (b) (6) | 07 Nov 2020 15:42:50 |
| User closed query 'Per ETRTR: Please confirm and amend date of test according to Preclaus Lab Portal data, thanks.' (Site from CRA). | (b) (4), (b) (6) | 07 Nov 2020 15:42:50 |
| Query 'Per ETRTR: Please confirm and amend date of test according to Preclaus Lab Portal data, thanks. answered with 'confirmed correct as entered' (Site from CRA). | Kim Hamilton (b) (4) | 06 Nov 2020 20:21:29 |
| User opened query 'Per ETRTR: Please confirm and amend date of test according to Preclaus Lab Portal data, thanks.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 19:03:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:10:06 |
| User entered '26 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:44:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:49:36

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:06 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:44:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:49:36

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:06 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:44:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:49:36

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:06 |
| User entered 'No (N)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:44:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:49:36

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:06 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:44:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:49:36

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:40 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:06 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:44:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:49:36

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:40 |
| User entered 'I' | System | 05 Nov 2020 20:44:48 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

Did the subject have Respiratory Rates ≥ 30 per Minute?

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| Query 'Next generate COVID page needs to be completed, please clarify.' canceled (Site from CRA). | (b) (4) (b) (4), (b) (6) | 11 Mar 2021 16:31:44 |
| User opened query 'Next generate COVID page needs to be completed, please clarify.' (Site from CRA). | (b) (4), (b) (6) | 23 Feb 2021 17:46:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 05 Nov 2020 20:50:21 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 05 Nov 2020 20:50:21 |
| User entered 'No (N)' reason for change: Data Entry Error | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:21 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 05 Nov 2020 20:50:01 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

[Start Date](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 15:36:27 |
| User closed query 'This is not the field for O2. This is start date if subject had RR >=30 which you noted NO to. Please remove date as previously requested.' (Site from CRA). | (b) (4), (b) (6) | 09 Nov 2020 15:36:25 |
| Query 'This is not the field for O2. This is start date if subject had RR >=30 which you noted NO to. Please remove date as previously requested.' answered with 'REMOVED' (Site from CRA). | April Green (b) (4) (b) (4) | 09 Nov 2020 14:02:50 |
| DataPoint Un-verified. | April Green (b) (4) | 09 Nov 2020 14:02:31 |
| User entered empty; reason for change Data Entry Error | (b) (4) April Green (b) (4) (b) (4) | 09 Nov 2020 14:02:31 |
| User opened query 'This is not the field for O2. This is start date if subject had RR >=30 which you noted NO to. Please remove date as previously requested.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 21:41:12 |
| User closed query 'Per ETRTR: Start date Data point should be filled only if answer is Yes. Please confirm and correct as applicable, thanks.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 21:41:12 |
| Query 'Per ETRTR: Start date Data point should be filled only if answer is Yes. Please confirm and correct as applicable, thanks.' answered with 'information is captured regarding oxygen saturation' (Site from CRA). | Kim Hamilton (b) (4) | 06 Nov 2020 20:26:05 |
| User opened query 'Per ETRTR: Start date Data point should be filled only if answer is Yes. Please confirm and correct as applicable, thanks.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 19:06:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User entered '26 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

Did the subject have Heart Rate \geq 125 beats per minute

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 05 Nov 2020 20:50:39 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 05 Nov 2020 20:50:39 |
| User entered 'No (N)' reason for change: Data Entry Error | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:39 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 05 Nov 2020 20:50:01 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

[Heart Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 15:36:27 |
| User closed query 'Please verify as symptom log notes O2 of 91% on 31Oct2020 and 93% a couple days later.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 21:41:17 |
| Query 'Please verify as symptom log notes O2 of 91% on 31Oct2020 and 93% a couple days later.' answered with 'corrected' (Site from CRA). | Kim Hamilton (b) (4) | 06 Nov 2020 20:26:34 |
| DataPoint Un-verified. | Kim Hamilton (b) (4) | 06 Nov 2020 20:23:36 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Kim Hamilton (b) (4) | 06 Nov 2020 20:23:36 |
| User opened query 'Please verify as symptom log notes O2 of 91% on 31Oct2020 and 93% a couple days later.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 19:37:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User entered 'No (N)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

[Start Date](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 15:36:27 |
| DataPoint Un-verified. | Kim Hamilton (b) (4) | 06 Nov 2020 20:24:57 |
| User entered '31 Oct 2020' reason for change: Data Entry Error | Kim Hamilton (b) (4) | 06 Nov 2020 20:24:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

[End Date](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 15:36:27 |
| DataPoint Un-verified. | Kim Hamilton (b) (4) | 06 Nov 2020 20:24:57 |
| User entered '03 Nov 2020' reason for change: Data Entry Error | Kim Hamilton (b) (4) | 06 Nov 2020 20:24:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

US3452332

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:49:36

[Oxygen Saturation](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 15:36:27 |
| DataPoint Un-verified. | Kim Hamilton (b) (4) | 06 Nov 2020 20:24:57 |
| User entered '91' reason for change: Data Entry Error | Kim Hamilton (b) (4) | 06 Nov 2020 20:24:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:10:21 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
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| User entered 'No (N)' | April Green (b) (4) (b) (4) | 05 Nov 2020 20:50:01 |

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[Start Date](#)

| Audit | User | Time (GMT) |
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| Audit | User | Time (GMT) |
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[PaO2](#)

| Audit | User | Time (GMT) |
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[Did the subject have Respiratory failure?](#)

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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[High-Flow Oxygen?](#)

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[Non-Invasive Ventilation?](#)

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[Mechanical Ventilation?](#)

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[ECMO?](#)

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:17:56 |
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[Evidence of Shock Requires](#)

[Vasopressors](#)

| Audit | User | Time (GMT) |
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[Acute Renal Dysfunction?](#)

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[Hepatic Dysfunction?](#)

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[Neurologic Dysfunction?](#)

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[Clinical Evidence](#)

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[Radiographical Evidence](#)

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[Admission to an intensive care unit due to SARS-CoV-2](#)

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[Generate Next COVID-19 Assessment](#)

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| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:18:04 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Mar 2021 16:31:49 |
| User entered 'No (N)' | Kim Hamilton (b) (4) | 10 Mar 2021 22:57:03 |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:49:36

[Visit](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | April Green (b) (4) (b) (4) | 10 Nov 2020 16:14:23 |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:49:36

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| User entered 'Yes (Y)' | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:49:36

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| User entered '28 Oct 2020' | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:49:36

[Visit](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | April Green (b) (4) (b) (4) | 10 Nov 2020 16:14:23 |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:49:36

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| | | |
| DataPoint Un-verified. | April Green (b) (4) | 16 Dec 2020 18:31:16 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | April Green (b) (4) | 16 Dec 2020 18:31:16 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| | | |
| User entered 'Yes (Y)' | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:49:36

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 and 01,03,08NOV2020 is recorded under Illness Visit Day 5,7,9,14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Dec 2020 18:58:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 and 01,03,08NOV2020 is recorded under Illness Visit Day 5,7,9,14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'corrected' (Site from DM). | April Green (b) (4) (b) (4) | 16 Dec 2020 18:31:23 |
| DataPoint Un-verified. | April Green (b) (4) (b) (4) | 16 Dec 2020 18:31:16 |
| User entered empty; reason for change Data Entry Error | April Green (b) (4) (b) (4) | 16 Dec 2020 18:31:16 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 and 01,03,08NOV2020 is recorded under Illness Visit Day 5,7,9,14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 04 Dec 2020 07:40:05 |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:49:36

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 and 01,03,08NOV2020 is recorded under Illness Visit Day 5,7,9,14,21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM). | (b) (4), (b) (6) | 04 Dec 2020 07:39:40 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 and 01,03,08NOV2020 is recorded under Illness Visit Day 5,7,9,14,21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 04 Dec 2020 07:39:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| User entered '30 Oct 2020' | April Green (b) (4) (b) (4) | 10 Nov 2020 16:14:23 |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:49:36

[Visit](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | April Green (b) (4) (b) (4) | 10 Nov 2020 16:14:23 |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:49:36

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| | | |
| DataPoint Un-verified. | April Green (b) (4) | 16 Dec 2020 18:31:40 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | April Green (b) (4) | 16 Dec 2020 18:31:40 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| | | |
| User entered 'Yes (Y)' | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:49:36

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| DataPoint Un-verified. | April Green (b) (4) | 16 Dec 2020 18:31:40 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | April Green (b) (4) | 16 Dec 2020 18:31:40 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| | | |
| User entered '01 Nov 2020' | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:49:36

[Visit](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | April Green (b) (4) (b) (4) | 10 Nov 2020 16:14:23 |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:49:36

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| | | |
| DataPoint Un-verified. | April Green (b) (4) | 16 Dec 2020 18:32:14 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | April Green (b) (4) | 16 Dec 2020 18:32:14 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| | | |
| User entered 'Yes (Y)' | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:49:36

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| | | |
| DataPoint Un-verified. | April Green (b) (4) | 16 Dec 2020 18:32:14 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | April Green (b) (4) | 16 Dec 2020 18:32:14 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| | | |
| User entered '03 Nov 2020' | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:49:36

[Visit](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | April Green (b) (4) (b) (4) | 10 Nov 2020 16:14:23 |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:49:36

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| | | |
| DataPoint Un-verified. | April Green (b) (4) | 16 Dec 2020 18:32:31 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | April Green (b) (4) | 16 Dec 2020 18:32:31 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| | | |
| User entered 'Yes (Y)' | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:49:36

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Per GCL Lab Reconciliation: Re-query: Previous query response indicates, "corrected", however, the Saliva samples with Collection Dates of 15NOV2020 and 23NOV2020 are still missing in EDC. Please clarify and update if appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 04:50:35 |
| Query 'Per GCL Lab Reconciliation: Re-query: Previous query response indicates, "corrected", however, the Saliva samples with Collection Dates of 15NOV2020 and 23NOV2020 are still missing in EDC. Please clarify and update if appropriate.' answered with 'THEY WERE NOT DONE' (Site from DM). | Kim Hamilton (b) (4) | 02 Apr 2021 19:41:15 |
| User opened query 'Per GCL Lab Reconciliation: Re-query: Previous query response indicates, "corrected", however, the Saliva samples with Collection Dates of 15NOV2020 and 23NOV2020 are still missing in EDC. Please clarify and update if appropriate.' (Site from DM). | (b) (4), (b) (6) | 18 Dec 2020 18:59:47 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,23NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 18 Dec 2020 18:59:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,23NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'corrected' (Site from DM). | April Green (b) (4) (b) (4) | 16 Dec 2020 18:32:43 |
| DataPoint Un-verified. | April Green (b) (4) (b) (4) | 16 Dec 2020 18:32:31 |
| User entered empty; reason for change Data Entry Error | April Green (b) (4) (b) (4) | 16 Dec 2020 18:32:31 |

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:49:36

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,23NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) (b) (4) | 02 Dec 2020 08:38:10 |
| | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| User entered '08 Nov 2020' | April Green (b) (4) (b) (4) | 10 Nov 2020 16:14:23 |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:49:36

[Visit](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | April Green (b) (4) (b) (4) | 10 Nov 2020 16:14:23 |

US3452332

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:49:36

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User closed query 'Per source visit has been completed, please answer yes or no, thanks.' (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 14:46:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Apr 2021 14:40:24 |
| Query 'Per source visit has been completed, please answer yes or no, thanks.' answered with '.' (Site from CRA). | Kim Hamilton (b) (4) | 02 Apr 2021 19:42:45 |
| DataPoint Un-verified. | Kim Hamilton (b) (4) | 02 Apr 2021 19:42:32 |
| User entered 'No (N)' reason for change: Data Entry Error | Kim Hamilton (b) (4) | 02 Apr 2021 19:42:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 17:38:21 |
| User opened query 'Per source visit has been completed, please answer yes or no, thanks.' (Site from CRA). | (b) (4), (b) (6) | 06 Jan 2021 15:57:43 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Jan 2021 15:54:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 10 Nov 2020 20:43:03 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Nov 2020 16:40:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| Query 'Data is required. Please complete.' answered with 'once visit is completed. site will enter data' (Site from System). | April Green (b) (4) | 10 Nov 2020 16:14:38 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 10 Nov 2020 16:14:23 |
| User entered empty. | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:49:36

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 17:38:21 |
| | | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Jan 2021 15:54:04 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| | | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Nov 2020 16:40:37 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| | | |
| User entered empty. | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:49:36

[Visit](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | April Green (b) (4) (b) (4) | 10 Nov 2020 16:14:23 |

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:49:36

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 07 Apr 2021 14:40:24 |
| User closed query 'Per source visit has been completed, please answer yes or no, thanks.' (Site from CRA). | (b) (4), (b) (6) | 07 Apr 2021 14:39:53 |
| Query 'Per source visit has been completed, please answer yes or no, thanks.' answered with 'DONE' (Site from CRA). | Kim Hamilton (b) (4) | 02 Apr 2021 19:43:31 |
| DataPoint Un-verified. | Kim Hamilton (b) (4) | 02 Apr 2021 19:43:11 |
| User entered 'No (N)' reason for change: Data Entry Error | Kim Hamilton (b) (4) | 02 Apr 2021 19:43:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 17:38:21 |
| User opened query 'Per source visit has been completed, please answer yes or no, thanks.' (Site from CRA). | (b) (4), (b) (6) | 06 Jan 2021 15:57:58 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Jan 2021 15:56:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 10 Nov 2020 20:43:31 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Nov 2020 16:40:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| Query 'Data is required. Please complete.' answered with 'once visit is completed. site will enter data' (Site from System). | April Green (b) (4) | 10 Nov 2020 16:14:44 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 10 Nov 2020 16:14:23 |
| User entered empty. | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:49:36

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 17:38:21 |
| | | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Jan 2021 15:56:21 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 18:52:14 |
| | | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Nov 2020 16:40:18 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 16:39:32 |
| | | |
| User entered empty. | April Green (b) (4) | 10 Nov 2020 16:14:23 |
| | (b) (4) | |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Please reconcile saliva log as multiple required samples should have been collected to date.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:33:41 |
| Query 'Please reconcile saliva log as multiple required samples should have been collected to date.' answered with 'SAMPLE COLLECTED AND SHIPPED TO LAB' (Site from CRA). | April Green (b) (4) (b) (4) | 09 Nov 2020 14:12:29 |
| User opened query 'Please reconcile saliva log as multiple required samples should have been collected to date.' (Site from CRA). | (b) (4), (b) (6) | 07 Nov 2020 15:44:46 |
| User closed query 'Per ETRTR: Please complete data entry for Saliva Collection page, thanks.' (Site from CRA). | (b) (4), (b) (6) | 07 Nov 2020 15:44:08 |
| Query 'Per ETRTR: Please complete data entry for Saliva Collection page, thanks.' answered with 'this will be entered when subject returns for day 28' (Site from CRA). | Kim Hamilton (b) (4) | 06 Nov 2020 20:37:57 |
| User opened query 'Per ETRTR: Please complete data entry for Saliva Collection page, thanks.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 18:57:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:10:40 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:34:51 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Please confirm date of visit as lab portal shows site entered Illness Day 1 collection on 28Oct2020' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 19:33:43 |
| Query 'Please confirm date of visit as lab portal shows site entered Illness Day 1 collection on 28Oct2020' answered with 'SAMPLE COLLECTED AND SHIPPED TO LAB' (Site from CRA). | April Green (b) (4) (b) (4) | 09 Nov 2020 14:12:32 |
| User opened query 'Please confirm date of visit as lab portal shows site entered Illness Day 1 collection on 28Oct2020' (Site from CRA). | (b) (4), (b) (6) | 07 Nov 2020 15:44:03 |
| User closed query 'Per ETRTR: Please reconcile Date recorded in Illness Visit Day 1 folder according to Preclarus Lab Portal report, thanks.' (Site from CRA). | (b) (4), (b) (6) | 07 Nov 2020 15:44:03 |
| Query 'Per ETRTR: Please reconcile Date recorded in Illness Visit Day 1 folder according to Preclarus Lab Portal report, thanks.' answered with 'data correct as entered. Lab was collected on 10/26/2020' (Site from CRA). | Kim Hamilton (b) (4) | 06 Nov 2020 20:39:05 |
| User opened query 'Per ETRTR: Please reconcile Date recorded in Illness Visit Day 1 folder according to Preclarus Lab Portal report, thanks.' (Site from CRA). | (b) (4), (b) (6) | 06 Nov 2020 18:56:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:10:40 |
| User entered '26 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:34:51 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:10:40 |
| User entered 'Clinic (Clinic)' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:34:51 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User entered 'SICKD1' | System | 05 Nov 2020 21:34:51 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered '26 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered '13:16' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User entered '26 Oct 2020 13:16' | System | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered '69.2' in | April Green (b) (4) | 05 Nov 2020 21:35:46 |
| DataPoint set to visible. | (b) (4) System | 05 Nov 2020 21:34:51 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered '222' lb | April Green (b) (4) | 05 Nov 2020 21:35:46 |
| DataPoint set to visible. | (b) (4) System | 05 Nov 2020 21:34:51 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered '98.7' F | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered 'Oral (Oral)' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered empty. | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered '74' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User entered 'bpm' | System | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered '12' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User entered 'breaths/min' | System | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered '122' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User entered 'mmHg' | System | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:06 |
| User entered '74' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User entered 'mmHg' | System | 05 Nov 2020 21:35:46 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| | | |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| | | |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:14 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:59 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:14 |
| User entered '26 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:35:59 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:49:36

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:11:19 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:36:13 |

US3452332

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:49:36

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 16:41:31 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 26 OCT 2020 is reported under illness visit Day 1 in EDC, however the sample dated 28 OCT 2020 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Nov 2020 09:49:47 |
| Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 26 OCT 2020 is reported under illness visit Day 1 in EDC, however the sample dated 28 OCT 2020 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'SITE WILL UPDATE LAB. THE CORRECT DATE OF VISIT IS 10/26/2020.' (Site from DM). | April Green (b) (4) (b) (4) | 09 Nov 2020 14:11:47 |
| User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 26 OCT 2020 is reported under illness visit Day 1 in EDC, however the sample dated 28 OCT 2020 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM). | (b) (4), (b) (6) | 09 Nov 2020 06:55:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:11:19 |
| User entered '26 Oct 2020' | April Green (b) (4) (b) (4) | 05 Nov 2020 21:36:13 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:18 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:31 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:11:51 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:18 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:31 |
| User entered '23 Nov 2020' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:11:51 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:18 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:31 |
| User entered 'Clinic (Clinic)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:11:51 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:18 |
| User entered 'SICKD28' | System | 23 Nov 2020 19:11:51 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered '23 Nov 2020' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered '10:23' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User entered '23 Nov 2020 10:23' | System | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered '69.2' in | April Green (b) (4) | 23 Nov 2020 19:17:03 |
| DataPoint set to visible. | (b) (4) System | 23 Nov 2020 19:11:51 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered '212.8' lb | April Green (b) (4) | 23 Nov 2020 19:17:03 |
| DataPoint set to visible. | (b) (4) System | 23 Nov 2020 19:11:51 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered '98.0' F | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered 'Oral (Oral)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered empty. | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered '71' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User entered 'bpm' | System | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered '16' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User entered 'breaths/min' | System | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered '138' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User entered 'mmHg' | System | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:40 |
| User entered '77' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| User entered 'mmHg' | System | 23 Nov 2020 19:17:03 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| | | |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:14 |
| | | |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:09 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:52 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:13 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:13:09 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 15:28:52 |
| User entered '23 Nov 2020' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:17:13 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:49:36

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:12:59 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:12:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 18:55:19 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:18:42 |

US3452332

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:49:36

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:12:59 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:12:57 |
| User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Dec 2020 09:22:01 |
| | (b) (4), (b) (6) | 16 Dec 2020 18:55:19 |
| Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'All labs have been sent to PPD.' (Site from DM). | April Green (b) (4) (b) (4) | 16 Dec 2020 18:40:25 |
| User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Dec 2020 08:12:01 |
| User entered '23 Nov 2020' | April Green (b) (4) (b) (4) | 23 Nov 2020 19:18:42 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 02 Feb 2021 18:32:15 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '02 Feb 2021' | Kim Calloway (b) (4) | 02 Feb 2021 18:32:15 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Clinic (Clinic)' | Kim Calloway (b) (4) | 02 Feb 2021 18:32:15 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'UNBLND_DECIDE' | System | 02 Feb 2021 18:32:15 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:36

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '02 Feb 2021' | Kim Calloway (b) (4) | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:36

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '0' | Kim Calloway (b) (4) | 05 Apr 2021 16:45:30 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 11:56:01 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:36

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:36

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | Kim Calloway (b) (4) | 05 Apr 2021 16:45:30 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 11:56:01 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:36

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '02 Feb 2021' | Kim Calloway (b) (4) | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:36

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Placebo (Placebo)' | Kim Calloway (b) (4) | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:36

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Placebo (Placebo)' | Kim Calloway (b) (4) | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:36

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Placebo (Placebo)' | Kim Calloway (b) (4) | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:36

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:36

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered '1' | System | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:36

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'I' | System | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

[Height](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered missing code ND - Not Done. | (b) (4) | 02 Feb 2021 19:37:03 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

[Weight](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered missing code ND - Not Done. | (b) (4) | 02 Feb 2021 19:37:03 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered empty. | System | 02 Feb 2021 19:37:03 |
| DataPoint set to visible. | System | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

[Height](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered missing code ND - Not Done. | (b) (4) | 02 Feb 2021 19:37:03 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

[Weight](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered missing code ND - Not Done. | (b) (4) | 02 Feb 2021 19:37:03 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered empty. | System | 02 Feb 2021 19:37:03 |
| DataPoint set to visible. | System | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Destiny | 02 Feb 2021 19:37:03 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Destiny Heinzig-Cartwright (b) (4) | 02 Feb 2021 19:37:03 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '02 Feb 2021' | (b) (4) | 02 Feb 2021 19:37:03 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '12:41' | (b) (4) | 02 Feb 2021 19:37:03 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered '02 Feb 2021 12:41' | System | 02 Feb 2021 19:37:03 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '98.4' F | Destiny Heinzig-Cartwright (b) (4) | 02 Feb 2021 19:37:03 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Oral (Oral)' | (b) (4) | 02 Feb 2021 19:37:03 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | Destiny | 02 Feb 2021 19:37:03 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '62' | (b) (4) | 02 Feb 2021 19:37:03 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'bpm' | System | 02 Feb 2021 19:37:03 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '16' | Destiny Heinzig-Cartwright (b) (4) | 02 Feb 2021 19:37:03 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'breaths/min' | System | 02 Feb 2021 19:37:03 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '151' | Destiny | 02 Feb 2021 19:37:03 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'mmHg' | System | 02 Feb 2021 19:37:03 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '88' | (b) (4) | 02 Feb 2021 19:37:03 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'mmHg' | System | 02 Feb 2021 19:37:03 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

[Height](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered missing code ND - Not Done. | (b) (4) | 02 Feb 2021 19:37:03 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

Weight

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered missing code ND - Not Done. | (b) (4) | 02 Feb 2021 19:37:03 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:36

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered empty. | System | 02 Feb 2021 19:37:03 |
| DataPoint set to visible. | System | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Feb 2021 20:10:18 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Destiny Heinzig-Cartwright (b) (4) | 02 Feb 2021 20:10:18 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '02 Feb 2021' | (b) (4) | 02 Feb 2021 20:10:18 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '13:47' | (b) (4) | 02 Feb 2021 20:10:18 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered '02 Feb 2021 13:47' | System | 02 Feb 2021 20:10:18 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '98.8' F | Destiny Heinzig-Cartwright (b) (4) | 02 Feb 2021 20:10:18 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Oral (Oral)' | (b) (4) | 02 Feb 2021 20:10:18 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | (b) (4) | 02 Feb 2021 20:10:18 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '87' | Destiny | 02 Feb 2021 20:10:18 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'bpm' | System | 02 Feb 2021 20:10:18 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '16' | Destiny Heinzig-Cartwright (b) (4) | 02 Feb 2021 20:10:18 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'breaths/min' | System | 02 Feb 2021 20:10:18 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '154' | (b) (4) | 02 Feb 2021 20:10:18 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'mmHg' | System | 02 Feb 2021 20:10:18 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '87' | Destiny | 02 Feb 2021 20:10:18 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'mmHg' | System | 02 Feb 2021 20:10:18 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Destiny Heinzig-Cartwright (b) (4) | 02 Feb 2021 19:37:28 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '02 Feb 2021' | (b) (4) | 02 Feb 2021 19:37:28 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Destiny Heinzig-Cartwright (b) (4) | 02 Feb 2021 19:38:21 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | (b) (4) | 02 Feb 2021 19:38:21 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | (b) (4) | 02 Feb 2021 19:38:21 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'mRNA-1273' | System | 02 Feb 2021 19:38:21 |
| DataPoint set to visible. | System | 02 Feb 2021 18:32:27 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '2 Feb 2021' | (b) (4) | 02 Feb 2021 19:38:21 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '13:14' | (b) (4) | 02 Feb 2021 19:38:21 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered '2 Feb 2021 13:14' | System | 02 Feb 2021 19:38:21 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|--------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Right Arm (RIGHT ARM)' | Destiny | 02 Feb 2021 19:38:21 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'ONCE' | System | 02 Feb 2021 19:38:21 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'INTRAMUSCULAR' | System | 02 Feb 2021 19:38:21 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | (b) (4) | 02 Feb 2021 19:38:57 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '02 Feb 2021' | (b) (4) | 02 Feb 2021 19:38:57 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '12:46' | (b) (4) | 02 Feb 2021 19:38:57 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered '02 Feb 2021 12:46' | System | 02 Feb 2021 19:38:57 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:36

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | (b) (4) | 02 Feb 2021 19:39:14 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:36

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '2 Feb 2021' | (b) (4) | 02 Feb 2021 19:39:14 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:36

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '12:47' | (b) (4) | 02 Feb 2021 19:39:14 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:36

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered '2 Feb 2021 12:47' | System | 02 Feb 2021 19:39:14 |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | (b) (4) | 02 Feb 2021 19:39:21 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'I' | System | 02 Feb 2021 19:39:21 |

US3452332

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 09 Feb 2021 20:28:54 |

US3452332

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '9 Feb 2021' | Chalimar Rojo (b) (4) | 09 Feb 2021 20:28:54 |

US3452332

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Contact Made (CONTACT MADE)' | Chalimar Rojo (b) (4) | 09 Feb 2021 20:28:54 |

US3452332

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | Chalimar Rojo (b) (4) | 09 Feb 2021 20:28:54 |

US3452332

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 09 Feb 2021 20:28:43 |

US3452332

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'I' | System | 09 Feb 2021 20:28:43 |

US3452332

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered '1' | System | 09 Feb 2021 20:28:43 |
| DataPoint set to visible. | System | 09 Feb 2021 20:28:43 |

US3452332

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Mar 2021 19:13:48 |

US3452332

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '03 Mar 2021' | Kim Calloway (b) (4) | 03 Mar 2021 19:13:48 |

US3452332

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Clinic (Clinic)' | Kim Calloway (b) (4) | 03 Mar 2021 19:13:48 |

US3452332

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'OLD29' | System | 03 Mar 2021 19:13:48 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Kim Calloway (b) (4) (b) (4) | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '03 Mar 2021' | Kim Calloway (b) (4) | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '11:43' | Kim Calloway (b) (4) | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered '03 Mar 2021 11:43' | System | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '97.9' F | Kim Calloway (b) (4) | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Oral (Oral)' | Kim Calloway (b) (4) | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | Kim Calloway (b) (4) | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '67' | Kim Calloway (b) (4) | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'bpm' | System | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '16' | Kim Calloway (b) (4) | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'breaths/min' | System | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '142' | Kim Calloway (b) (4) | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'mmHg' | System | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '87' | Kim Calloway (b) (4) | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'mmHg' | System | 03 Mar 2021 19:16:33 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Kim Calloway (b) (4) (b) (4) | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '03 Mar 2021' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '13:05' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered '03 Mar 2021 13:05' | System | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '97.8' F | Kim Calloway (b) (4) | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Oral (Oral)' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | Kim Calloway (b) (4) | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '79' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'bpm' | System | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '16' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'breaths/min' | System | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '130' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'mmHg' | System | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '71' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'mmHg' | System | 03 Mar 2021 19:17:02 |

US3452332

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:16 |

US3452332

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '03 Mar 2021' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:16 |

US3452332

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:35 |

US3452332

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | Kim Calloway (b) (4) | 03 Mar 2021 19:17:35 |

US3452332

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | Kim Calloway (b) (4) | 03 Mar 2021 19:17:35 |

US3452332

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'mRNA-1273' | System | 03 Mar 2021 19:17:35 |
| DataPoint set to visible. | System | 09 Feb 2021 20:28:43 |

US3452332

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '03 Mar 2021' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:35 |

US3452332

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '12:23' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:35 |

US3452332

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered '03 Mar 2021 12:23' | System | 03 Mar 2021 19:17:35 |

US3452332

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|--------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Right Arm (RIGHT ARM)' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:35 |

US3452332

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'ONCE' | System | 03 Mar 2021 19:17:35 |

US3452332

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:36

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'INTRAMUSCULAR' | System | 03 Mar 2021 19:17:35 |

US3452332

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 03 Mar 2021 19:17:46 |

US3452332

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'I' | System | 03 Mar 2021 19:17:46 |

US3452332

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 24 Mar 2021 19:51:41 |

US3452332

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered '11 Mar 2021' | Chalimar Rojo (b) (4) | 24 Mar 2021 19:51:41 |

US3452332

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Contact Made (CONTACT MADE)' | Chalimar Rojo (b) (4) | 24 Mar 2021 19:51:41 |

US3452332

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:36

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered empty. | Chalimar Rojo (b) (4) | 24 Mar 2021 19:51:41 |

US3452332

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| User entered 'Yes (Y)' | Chalimar Rojo (b) (4) | 24 Mar 2021 19:51:32 |

US3452332

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:36

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:50:56 |
| User entered 'I' | System | 24 Mar 2021 19:51:32 |

US3452332

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 08 Apr 2021 15:52:10 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered '08 Apr 2021' | Kim Calloway (b) (4) | 08 Apr 2021 15:52:10 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Kim Calloway (b) (4) | 08 Apr 2021 15:52:10 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:36

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| User entered 'OLD57' | System | 08 Apr 2021 15:52:10 |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'No (N)' | Kim Calloway (b) (4) | 08 Apr 2021 15:52:20 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 08 Apr 2021 15:52:20 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 08 Apr 2021 15:52:20 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 15:52:20 |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 08 Apr 2021 15:52:20 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 08 Apr 2021 15:52:20 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 08 Apr 2021 15:52:20 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 08 Apr 2021 15:52:20 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 15:52:20 |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 08 Apr 2021 15:52:20 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 15:52:20 |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 08 Apr 2021 15:52:20 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 15:52:20 |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered empty. | Kim Calloway (b) (4) | 08 Apr 2021 15:52:20 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:36

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 15:52:20 |

US3452332

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 08 Apr 2021 15:52:30 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:36

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered '08 Apr 2021' | Kim Calloway (b) (4) | 08 Apr 2021 15:52:30 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 08 Apr 2021 15:52:47 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered '08 Apr 2021' | Kim Calloway (b) (4) | 08 Apr 2021 15:52:47 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| User entered '09:16' | Kim Calloway (b) (4) | 08 Apr 2021 15:52:47 |
| | (b) (4) | |

US3452332

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:36

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '08 Apr 2021 09:16' | System | 08 Apr 2021 15:52:47 |

US3452332

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:49:36

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 14:02:57 |
| User closed query 'Per CDM: Per the diary from Diary Dose2, Medical attention is YES on Days 41, 42, 43 after dosing. Please review and if correct, please agree to add a solicited AE to the AE page for which Medical attention was given or else clarify. | (b) (4), (b) (6) | 21 Apr 2021 07:32:22 |
| ' (Site from DM). Query 'Per CDM: Per the diary from Diary Dose2, Medical attention is YES on Days 41, 42, 43 after dosing. Please review and if correct, please agree to add a solicited AE to the AE page for which Medical attention was given or else clarify. | April Green (b) (4) (b) (4) | 20 Apr 2021 16:57:05 |
| ' answered with 'SUBJECT DID NOT SEEK MEDICAL ATTENTION.' (Site from DM). User opened query 'Per CDM: Per the diary from Diary Dose2, Medical attention is YES on Days 41, 42, 43 after dosing. Please review and if correct, please agree to add a solicited AE to the AE page for which Medical attention was given or else clarify. | (b) (4), (b) (6) | 20 Apr 2021 05:59:45 |
| ' (Site from DM). User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 1; end date: Day 50). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 11:08:23 |
| User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 4; end date: Day 50). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 11:07:46 |

US3452332

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:49:36

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 4; end date: Day 50). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM). | Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:46:03 |
| Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 1; end date: Day 50). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM). | Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:45:57 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 4; end date: Day 50). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) (b) (4) | 28 Mar 2021 10:26:46 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 1; end date: Day 50). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) (b) (4) | 28 Mar 2021 10:26:36 |
| User signature succeeded. | Carl Griffin (b) (4) (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4) | 05 Nov 2020 22:07:49 |
| User entered 'Yes (Y)' | April Green (b) (4) (b) (4) | 02 Nov 2020 16:36:06 |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:25:35 |
| | | |
| User entered | System | 03 Nov 2020 15:25:30 |
| 'USA-US208-2020-mRNA-1273-P301000005' | | |
| User entered 'New' | (b) (4), (b) (6) | 03 Nov 2020 15:25:30 |
| | | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Nov 2020 23:44:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Nov 2020 23:44:48 |
| Data point term sent to Coder | System | 02 Nov 2020 16:38:23 |
| User entered 'COVID 19' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User closed query 'Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify. ' (Site from DM). | (b) (4), (b) (6) | 16 Apr 2021 11:17:59 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| Query 'Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify. ' answered with 'PER QUERY RESOLUTION UPDATED' (Site from DM). | (b) (4) Kim Calloway (b) (4) (b) (4) | 12 Apr 2021 14:13:48 |
| DataPoint Un-verified. | Kim Calloway (b) (4) | 12 Apr 2021 14:12:52 |
| Signature has been broken. | (b) (4) Kim Calloway (b) (4) | 12 Apr 2021 14:12:52 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) Kim Calloway (b) (4) | 12 Apr 2021 14:12:52 |
| User opened query 'Covid-19 AE present but Was this a medically-attended AE? Is marked NO. Please review and reconcile. Else clarify. ' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 23:23:56 |
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered 'No (N)' | April Green (b) (4) (b) (4) | 02 Nov 2020 16:38:20 |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 20:09:09 |
| User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM). | (b) (4), (b) (6) | 07 Nov 2020 19:16:35 |
| Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'corrected' (Site from DM). | April Green (b) (4) | 06 Nov 2020 18:26:08 |
| DataPoint Un-verified. | (b) (4) | |
| | April Green (b) (4) | 06 Nov 2020 18:25:56 |
| User entered 'No (N)' reason for change: Data Entry Error | April Green (b) (4) | 06 Nov 2020 18:25:56 |
| | (b) (4) | |
| User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM). | (b) (4), (b) (6) | 06 Nov 2020 10:56:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered 'Yes (Y)' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered 'Yes (Y)' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Dec 2020 17:43:15 |
| DataPoint Un-verified. | April Green (b) (4) | 10 Nov 2020 20:01:01 |
| | (b) (4) | |
| User entered '26 Oct 2020' reason for change: Data Entry Error | April Green (b) (4) | 10 Nov 2020 20:01:01 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| | | |
| User entered '24 Oct 2020' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered empty. | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Nov 2020 16:38:20 |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Dec 2020 17:43:15 |
| DataPoint Un-verified. | April Green (b) (4) | 23 Nov 2020 21:29:24 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | April Green (b) (4) | 23 Nov 2020 21:29:24 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| | | |
| User entered 'Yes (Y)' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Dec 2020 17:43:15 |
| DataPoint Un-verified. | April Green (b) (4) | 23 Nov 2020 21:29:24 |
| | (b) (4) | |
| User entered '23 Nov 2020' reason for change: Data Entry Error | April Green (b) (4) | 23 Nov 2020 21:29:24 |
| | (b) (4) | |
| User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). | (b) (4), (b) (6) | 21 Nov 2020 01:24:46 |
| Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'will do' (Site from Safety). | April Green (b) (4) | 19 Nov 2020 14:00:42 |
| | (b) (4) | |
| User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). | (b) (4), (b) (6) | 17 Nov 2020 14:58:22 |
| | | |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 18:09:49 |
| | | |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'not recovered' (Site from Safety). | April Green (b) (4) | 10 Nov 2020 20:01:32 |
| | (b) (4) | |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 18:07:57 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| | | |
| User entered empty. | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered empty. | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Nov 2020 16:38:20 |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered 'No (N)' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered '0' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered '0' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered '0' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered empty. | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered empty. | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered empty. | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered empty. | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered '0' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered '0' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered '0' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered 'Not Related (NOT RELATED)' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered 'Not Related (NOT RELATED)' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 02:39:29 |
| User closed query 'PV Query: As the last dose of mRNA-1273 was given on 03 Sep 2020 (prior to event onset), please update the action taken with mRNA-1273 from none to not applicable. If study drug has been given since 03 Sep 2020, please update the EDC accordingly.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 18:09:19 |
| Query 'PV Query: As the last dose of mRNA-1273 was given on 03 Sep 2020 (prior to event onset), please update the action taken with mRNA-1273 from none to not applicable. If study drug has been given since 03 Sep 2020, please update the EDC accordingly.' answered with '.' (Site from Safety). | April Green (b) (4) | 10 Nov 2020 20:03:10 |
| | (b) (4) | |
| DataPoint Un-verified. | April Green (b) (4) | 10 Nov 2020 20:03:00 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | April Green (b) (4) | 10 Nov 2020 20:03:00 |
| | (b) (4) | |
| User opened query 'PV Query: As the last dose of mRNA-1273 was given on 03 Sep 2020 (prior to event onset), please update the action taken with mRNA-1273 from none to not applicable. If study drug has been given since 03 Sep 2020, please update the EDC accordingly.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 18:07:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered 'None (NONE)' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

None

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 02 Nov 2020 16:40:40 |
| User entered '1' reason for change: Data Entry Error | April Green (b) (4) | 02 Nov 2020 16:40:40 |
| | (b) (4) | |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 02 Nov 2020 16:38:20 |
| User entered '0' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered '0' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered '0' | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Outcome](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Dec 2020 17:43:15 |
| DataPoint Un-verified. | April Green (b) (4) | 23 Nov 2020 21:29:24 |
| | (b) (4) | |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | April Green (b) (4) | 23 Nov 2020 21:29:24 |
| Data Entry Error | (b) (4) | |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 21 Nov 2020 01:24:58 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'will do' (Site from Safety). | April Green (b) (4) | 19 Nov 2020 14:01:03 |
| | (b) (4) | |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 17 Nov 2020 14:58:41 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 18:10:01 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'not recovered' (Site from Safety). | April Green (b) (4) | 10 Nov 2020 20:02:10 |
| | (b) (4) | |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 18:08:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | April Green (b) (4) (b) (4) | 02 Nov 2020 16:38:20 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered empty. | April Green (b) (4) | 02 Nov 2020 16:38:20 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Narrative](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 13 Mar 2021 17:22:54 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 18:09:34 |
| User closed query 'PV Query: Please complete the appropriate Symptom logs for Covid-19 Assessments.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 18:09:30 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'none at this point' (Site from Safety). | April Green (b) (4) (b) (4) | 10 Nov 2020 20:02:48 |
| Query 'PV Query: Please complete the appropriate Symptom logs for Covid-19 Assessments.' answered with 'completed' (Site from Safety). | April Green (b) (4) (b) (4) | 10 Nov 2020 20:02:20 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 20:09:22 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 18:08:39 |
| User opened query 'PV Query: Please complete the appropriate Symptom logs for Covid-19 Assessments.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 18:07:06 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User closed query 'Per DM CLR: SAE Narrative = CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). | (b) (4), (b) (6) | 07 Nov 2020 19:16:40 |
| Query 'Per DM CLR: SAE Narrative = CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'corrected' (Site from DM). | April Green (b) (4) | 06 Nov 2020 18:26:54 |
| DataPoint Un-verified. | (b) (4) | |
| User entered 'PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. PATIENT RETURNED WITHIN 48 HOURS FOR ILLNESS VISIT. SYMPTOMS LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. PATIENT TESTED POSITIVE ON 26-OCT-2020. SUBJECT IN CONVALESCENT PERIOD NOW.' | April Green (b) (4) | 06 Nov 2020 18:26:43 |
| reason for change: Data Entry Error | (b) (4) | |
| User opened query 'Per DM CLR: SAE Narrative = CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). | (b) (4), (b) (6) | 06 Nov 2020 10:56:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:10 |
| User entered 'PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. PATIENT RETURNED WITHIN 48 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. PATIENT TESTED POSITIVE ON 26-OCT-2020. SUBJECT IN CONVALESCENT PERIOD NOW.' | April Green (b) (4) | 02 Nov 2020 16:38:20 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 02 Nov 2020 16:38:20 |

US3452332

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Apr 2021 14:12:52 |
| User entered '0' | System | 02 Nov 2020 16:38:20 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| | | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0. | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 02 Apr 2021 19:49:50 |
| Data point term sent to Coder | (b) (4) | |
| User entered 'joint aches' | System | 02 Apr 2021 19:49:13 |
| | Destiny | 02 Apr 2021 19:48:56 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'No (N)' | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'Yes (Y)' | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'No (N)' | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '03 Sep 2020' reason for change: Data Entry Error | (b) (4) | 02 Apr 2021 19:51:11 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |
| User entered '03 Oct 2020' | Destiny | 02 Apr 2021 19:48:56 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Apr 2021 19:51:53 |
| User entered '12:01' reason for change: Data Entry Error | Destiny Heinzig-Cartwright (b) (4) | 02 Apr 2021 19:51:53 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Apr 2021 19:51:11 |
| User entered empty. | System | 02 Apr 2021 19:51:11 |
| | Destiny | 02 Apr 2021 19:48:56 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| User entered '03 Sep 2020 12:01' | System | 02 Apr 2021 19:51:53 |
| User entered empty. | System | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'No (N)' | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '22 Oct 2020' | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Apr 2021 19:51:53 |
| User entered '00:00' reason for change: Data Entry Error | Destiny Heinzig-Cartwright (b) (4) | 02 Apr 2021 19:51:53 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Apr 2021 19:51:11 |
| User entered empty. | System | 02 Apr 2021 19:51:11 |
| | Destiny Heinzig-Cartwright (b) (4) | 02 Apr 2021 19:48:56 |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| User entered '22 Oct 2020 00:00' | System | 02 Apr 2021 19:51:53 |
| User entered empty. | System | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Severity](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'No (N)' | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | Destiny Heinzig-Cartwright (b) (4) | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'Related (RELATED)' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'None (NONE)' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

None

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'l' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Outcome](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:48:56 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| User entered '0' | System | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |
| User entered '0' | System | 02 Apr 2021 19:48:56 |

US3452332

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:04 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0. | Coder Import (b) (4) | 02 Apr 2021 19:52:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 02 Apr 2021 19:52:53 |
| Data point term sent to Coder | System | 02 Apr 2021 19:51:26 |
| User entered 'muscle aches' | Destiny | 02 Apr 2021 19:50:40 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'No (N)' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'Yes (Y)' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'No (N)' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '06 Sep 2020' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| User entered empty. | System | 02 Apr 2021 19:50:40 |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'No (N)' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:50:40 |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '22 Oct 2020' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| User entered empty. | System | 02 Apr 2021 19:50:40 |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Severity](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:50:40 |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'No (N)' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:50:40 |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:50:40 |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'Related (RELATED)' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:50:40 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'None (NONE)' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:50:40 |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

None

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | (b) (4) | 02 Apr 2021 19:50:47 |
| User entered '1' reason for change: Data Entry Error | Destiny | 02 Apr 2021 19:50:47 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 02 Apr 2021 19:50:40 |
| User entered '0' | Destiny | 02 Apr 2021 19:50:40 |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered '0' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:50:40 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Outcome](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Destiny Heinzig-Cartwright (b) (4) (b) (4) | 02 Apr 2021 19:50:40 |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 16:47:00 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| User entered empty. | (b) (4) | 02 Apr 2021 19:50:40 |
| | Destiny | |
| | Heinzig-Cartwright (b) (4) | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| User entered '0' | System | 02 Apr 2021 19:50:40 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |
| User entered '0' | System | 02 Apr 2021 19:50:40 |

US3452332

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:49:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 17:18:10 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:49:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 14:02:57 |
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 06 Nov 2020 18:02:41 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:18:34 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 18:20:22 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 18:20:22 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Aug 2020 18:19:28 |
| User entered 'ALPRAZOLAM' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'ANXIETY' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'I' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'mg (mg)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'as needed (PRN)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Oral (ORAL)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | 06 Nov 2020 18:02:31 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 13:16:38 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with '.' (Site from DM). | Kim Calloway (b) (4) | 19 Oct 2020 16:49:03 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 16 Oct 2020 11:54:03 |
| Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version. | | 21 Aug 2020 02:58:36 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 19 Aug 2020 18:19:08 |
| User entered 'UN UNK 2005' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '0' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:08 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Aug 2020 18:19:08 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Aug 2020 18:19:08 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Aug 2020 18:19:08 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---|--|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 18:21:32 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 18:21:32 |
| Data point term sent to Coder User entered 'AMLODIPINE' | System Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:20:31 19 Aug 2020 18:19:41 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'HIGH BLOOD PRESSURE' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '5' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'mg (mg)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'once daily (QD)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Oral (ORAL)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 02:58:36 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 19 Aug 2020 18:19:41 |
| User entered 'UN UNK 2005' | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:19:41 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '0' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:19:41 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Aug 2020 18:19:41 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Aug 2020 18:19:41 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Aug 2020 18:19:41 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 18:21:32 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 18:21:32 |
| Data point term sent to Coder | System | 19 Aug 2020 18:20:32 |
| User entered 'METFORMIN' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'DIABETES TYPE II' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '500' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'mg (mg)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'twice daily (BID)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Oral (ORAL)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 02:58:36 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 19 Aug 2020 18:20:16 |
| User entered 'UN Jun 2019' | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:20:16 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '0' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:16 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 19 Aug 2020 18:20:16 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Aug 2020 18:20:16 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Aug 2020 18:20:16 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 18:22:32 |
| | (b) (4) | |
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 19 Aug 2020 18:22:32 |
| User: Coder System - version | (b) (4) | |
| WHODrug-Global-B3\\202003. | | |
| Data point term sent to Coder | System | 19 Aug 2020 18:21:34 |
| User entered 'ROSUVASTATIN' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'HIGH CHOLESTEROL' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '20' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'mg (mg)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'once daily (QD)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Oral (ORAL)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 02:58:36 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 19 Aug 2020 18:20:53 |
| User entered 'UN UNK 2010' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '0' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:20:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Aug 2020 18:20:53 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Aug 2020 18:20:53 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Aug 2020 18:20:53 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---|--|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 18:22:33 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 18:22:33 |
| Data point term sent to Coder User entered 'IBUPROFEN' | System Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:21:35 19 Aug 2020 18:21:26 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'BACK PAIN' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '800' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'mg (mg)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'as needed (PRN)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Oral (ORAL)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 13:17:05 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with '.' (Site from DM). | Kim Calloway (b) (4) | 19 Oct 2020 16:49:47 |
| | (b) (4) | |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). | (b) (4), (b) (6) | 16 Oct 2020 11:55:10 |
| Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version. | | 21 Aug 2020 02:58:36 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 19 Aug 2020 18:21:26 |
| User entered 'UN UNK 2015' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '0' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:26 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Aug 2020 18:21:26 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Aug 2020 18:21:26 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Aug 2020 18:21:26 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Oct 2020 20:14:40 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Oct 2020 20:14:40 |
| | (b) (4) | |
| Data point term sent to Coder | System | 22 Oct 2020 12:11:57 |
| Coding entries removed. | Kim Calloway (b) (4) | 22 Oct 2020 12:11:49 |
| | (b) (4) | |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 18:23:59 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 18:23:59 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Aug 2020 18:22:36 |
| User entered 'FUROSEMIDE' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Indication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location and type of edema. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 13:17:12 |
| Query 'Per DM CLR: Please update the indication to reflect the location and type of edema. Review and update indication and ensure to update MH eCRF as appropriate. ' answered with ' ' (Site from DM). | Kim Calloway (b) (4) (b) (4) | 22 Oct 2020 12:11:59 |
| User entered 'EDEMA BOTH FEET' reason for change: Data Entry Error | Kim Calloway (b) (4) (b) (4) | 22 Oct 2020 12:11:49 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location and type of edema. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 05:25:06 |
| User entered 'EDEMA' | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:21:53 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '40' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'mg (mg)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'once daily (QD)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Oral (ORAL)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 02:58:36 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 19 Aug 2020 18:21:53 |
| User entered 'UN UNK 1995' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '0' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:21:53 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Aug 2020 18:21:53 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Aug 2020 18:21:53 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Aug 2020 18:21:53 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC GLYCOSIDES, ATC: DIGITALIS GLYCOSIDES, PRODUCT: DIGOXIN - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 19 Oct 2020 17:18:52 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 19 Oct 2020 17:18:52 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Oct 2020 16:54:06 |
| Coding entries removed. | Kim Calloway (b) (4) | 19 Oct 2020 16:53:52 |
| | (b) (4) | |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC GLYCOSIDES, ATC: DIGITALIS GLYCOSIDES, PRODUCT: DIGOXIN - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 20 Aug 2020 00:36:13 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 20 Aug 2020 00:36:13 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Aug 2020 18:22:38 |
| User entered 'DIGOXIN' | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'HYPERTENSION' reason for change: | Kim Calloway (b) (4) | 19 Oct 2020 16:53:52 |
| Data Entry Error | (b) (4) | |
| User entered 'HIGH BLOOD PRESSURE' | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '250' | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User closed 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. | (b) (4), (b) (6) | 04 Nov 2020 13:17:17 |
| ' (Site from DM). | | |
| 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. | Kim Calloway (b) (4) | 19 Oct 2020 16:53:30 |
| ' answered with '.' (Site from DM). | (b) (4) | |
| User entered 'ug (ug)' reason for change: Data Entry Error | Kim Calloway (b) (4) | 19 Oct 2020 16:53:26 |
| | (b) (4) | |
| 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. | (b) (4), (b) (6) | 16 Oct 2020 11:55:24 |
| ' (Site from DM). | | |
| User entered 'mg (mg)' | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'once daily (QD)' | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Oral (ORAL)' | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 02:58:36 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 19 Aug 2020 18:22:21 |
| User entered 'UN UNK 1995' | Kim Calloway (b) (4) (b) (4) | 19 Aug 2020 18:22:21 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered '0' | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'Yes (Y)' | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered empty. | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 16 Apr 2021 03:19:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Nov 2020 18:02:31 |
| User entered 'No (N)' | Kim Calloway (b) (4) | 19 Aug 2020 18:22:21 |
| | (b) (4) | |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Aug 2020 18:22:21 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Aug 2020 18:22:21 |

US3452332

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:36

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Aug 2020 18:22:21 |

US3452332

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:49:36

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:12:57 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Mar 2021 19:57:40 |
| User entered 'No (N)' | April Green (b) (4) | 05 Feb 2021 15:32:34 |
| | (b) (4) | |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered | System | 03 Nov 2020 15:25:30 |
| 'USA-US208-2020-MRNA-1273-P301000005' | | |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 18:10:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| User entered 'US' | System | 03 Nov 2020 15:26:19 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 28 Dec 2020 23:12:42 |
| User entered '3' | System | 21 Nov 2020 01:26:12 |
| User entered '2' | System | 11 Nov 2020 18:10:37 |
| User entered '1' | System | 03 Nov 2020 15:26:19 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered | System | 03 Nov 2020 15:25:30 |
| 'USA-US208-2020-MRNA-1273-P301000005' | | |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 18:10:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| User entered 'US' | System | 03 Nov 2020 15:26:19 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 28 Dec 2020 23:12:42 |
| User entered '3' | System | 21 Nov 2020 01:26:12 |
| User entered '2' | System | 11 Nov 2020 18:10:37 |
| User entered '1' | System | 03 Nov 2020 15:26:19 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:49:36

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| User entered '03/Nov/2020 10:26' | System | 03 Nov 2020 15:26:19 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:49:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Nov 2020 18:10:23 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| User entered 'I' | (b) (4), (b) (6) | 03 Nov 2020 15:26:19 |
| | | |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| User entered | | |
| 'USA-US208-2020-MRNA-1273-P301000005' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

Death

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 18:10:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| User entered 'US' | System | 03 Nov 2020 15:26:19 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 28 Dec 2020 23:12:42 |
| User entered '3' | System | 21 Nov 2020 01:26:12 |
| User entered '2' | System | 11 Nov 2020 18:10:37 |
| User entered '1' | System | 03 Nov 2020 15:26:19 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:49:36

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 02:39:12 |
| User entered '11/Nov/2020 13:10' | System | 11 Nov 2020 18:10:37 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:49:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 02:39:12 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Nov 2020 01:25:31 |
| | | |
| User entered 'I' | (b) (4), (b) (6) | 11 Nov 2020 18:10:37 |
| | | |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered | System | 03 Nov 2020 15:25:30 |
| 'USA-US208-2020-MRNA-1273-P301000005' | | |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 18:10:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| User entered 'US' | System | 03 Nov 2020 15:26:19 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 28 Dec 2020 23:12:42 |
| User entered '3' | System | 21 Nov 2020 01:26:12 |
| User entered '2' | System | 11 Nov 2020 18:10:37 |
| User entered '1' | System | 03 Nov 2020 15:26:19 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:49:36

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 02:39:12 |
| User entered '20/Nov/2020 20:26' | System | 21 Nov 2020 01:26:12 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:49:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 28 Dec 2020 23:12:30 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 02:39:12 |
| | | |
| User entered 'I' | (b) (4), (b) (6) | 21 Nov 2020 01:26:12 |
| | | |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| User entered | | |
| 'USA-US208-2020-MRNA-1273-P301000005' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 15:26:05 |
| | | |
| User entered 'No (N)' | System | 03 Nov 2020 15:25:30 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 18:10:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 05 Nov 2020 22:08:42 |
| User entered 'US' | System | 03 Nov 2020 15:26:19 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:49:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 28 Dec 2020 23:12:42 |
| User entered '3' | System | 21 Nov 2020 01:26:12 |
| User entered '2' | System | 11 Nov 2020 18:10:37 |
| User entered '1' | System | 03 Nov 2020 15:26:19 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:49:36

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Feb 2021 17:43:19 |
| User entered '28/Dec/2020 18:12' | System | 28 Dec 2020 23:12:42 |

US3452332

Folder: SAE USA-US208-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:49:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Carl Griffin (b) (4) | 17 Apr 2021 15:13:33 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Feb 2021 17:43:19 |
| | | |
| User entered 'I' | (b) (4), (b) (6) | 28 Dec 2020 23:12:42 |
| | | |